RESPIRATORY CARE BOARD OF CALIFORNIA'S PROPOSAL
TO THE SENATE COMMITTEE ON BUSINESS AND PROFESSIONS
FOR THE REGULATION OF

POLYSOMNOGRAPHIC TECHNOLOGISTS
2006

SECTION A: APPLICANT GROUP IDENTIFICATION

1. WHAT OCCUPATIONAL GROUP IS SEEKING REGULATION? IDENTIFY BY NAME, ADDRESS AND ASSOCIATIONAL AFFILIATION THE INDIVIDUALS WHO SHOULD BE CONTACTED WHEN COMMUNICATING WITH THIS GROUP REGARDING THIS APPLICATION.

The **Respiratory Care Board of California [RCB]** is seeking to establish a separate license category to regulate polysomnographic technologists.

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The RCB is mandated to protect the public from the unauthorized and unqualified practice of respiratory care and from unprofessional conduct by persons licensed to practice respiratory care. The practice of respiratory care is coiled throughout the relatively new and emerging practice of polysomnography - - the collective process of attended monitoring and recording physiologic data during sleep, including sleep-related respiratory disturbances, for the purposes of identifying and assisting in the treatment of sleep/wake disorders (e.g. sleep apnea, narcolepsy, restless legs syndrome, etc...). Over the last several years, the RCB has reviewed this matter[1] in detail weighing such factors as: 1) the level of harm of unlicensed practice by various credentialed and non-credentialed technicians, 2) existing industry standards, 3) the demand for sleep studies, 4) the demand for respiratory therapists, and 5) the position statements and comments from interested parties. As a result, the RCB found the most effective alternative to protect the public from the unlicensed and/or unqualified practices of respiratory care and polysomnography is to establish a new licensure category for "Polysomnographic Technologists."

[1] In 2001, the Board noted its concern with the unlicensed practice of respiratory care as it relates to polysomnography, in its report to the then, Joint Legislative Sunset Review Committee (JLSRC). In response, the JLSRC included in its 2002 recommendations to support the Board's effort to review the function and skill of currently unlicensed technicians and further study to determine the need for regulation.

While interest in sleep theories has been around for centuries, sleep studies and disorders as they relate to medicine is a relatively new field emerging by leaps and bounds in the last decade. Literature indicates sleep studies were introduced into the medical community in the mid-1970s. One of the first well-recognized sleep associations was founded in the 1970s and several associations followed thereafter. National certification for sleep technicians was available as early as 1979 (though accreditation of this certification program, by the National Organization for Competency Assurance, was not obtained until 2002). Sleep medicine began to expand rapidly in the late 1980s and again in 1996 when the American Medical Association recognized sleep medicine as a specialty.

In recent years, there has been an explosion of new sleep testing programs. It is believed that sleep labs are opening regularly because there are no requirements for the set-up or operation of facilities, there is a demand for sleep testing, and there is significant income to be gained. Results to a survey issued by the Board in 2004 (discussed later) indicate that over half of respondents agreed that the demand for polysomnography services is greater than California facilities can currently provide. In an article titled "Conundrums in Sleep Medicine," published in a 1999 issue of *CHEST Magazine*, Nancy A. Collop, MD, FCCP writes:

> "Sleep laboratories are opening regularly in this country. What is required to set up a sleep laboratory? Money and a building! Anyone can open a sleep laboratory, and it seems that just about everyone is. In the small city of Charleston where I reside, there are at least seven sleep laboratories run by a variety of specialists, including ear, nose, and throat; pulmonologists; and neurologists. Many of these physicians do not have any specific training in sleep medicine. There is also a lack of quality control in sleep laboratories. In some labs, technicians "score" the sleep study, and the physician never actually reviews the study, but only develops an interpretation based on the scores. Portable sleep studies are also being performed with even less quality control. What is the reason for the popularity of sleep laboratories? ***Patients and income***. ..."

Through an Internet site [www.corfnet.net], a company touts their ability to help investors in lucrative business opportunities by opening various health centers including sleep laboratories. **They even provide that physician and polysomnographer services can be "purchased."** The South Florida Medical Management advertises to "assist healthcare providers and investors in broadening their scope of services and maximizing the use of their existing facilities by developing sleep labs/centers as a compliment to their practice location or as an adjacent structure." The internet site provides that the cost of these programs vary depending upon many factors including "whether or not the owners have a resident physician & polysomnographer or will need to purchase these services."

The rising number of new sleep programs and demand for sleep services has contributed to the growing number of unlicensed personnel practicing respiratory care as it relates to polysomnography. In California, it is estimated that 65% of the "sleep technicians" are ***unlicensed personnel***, while 30% of the workforce are *licensed* respiratory care practitioners (and 5% are other licensed healthcare workers).

Pamela K. Minkley, CPFT, RRT, RPSGT, described the technology used in polysomnography in an article titled "Respiratory Care Practitioners and Sleep Medicine: Opportunities and Challenges," published in the May 1998 issue of *Respiratory Care*. She wrote:

> "Polysomnography borrows and adapts technology from electroneurodiagnostics, *pulmonary diagnostics, respiratory care*, biomedical science, and other fields. It requires adaptation of clinical aspects of neurology, pulmonary, and sleep medicine with aspects of gastrointestinal medicine, ear, nose, and throat medicine, urology, psychiatry, psychology, and social work. It is an amalgamation of skills that is a specialty unto itself - sleep medicine and technology.... **Respiratory care and electroneurodiagnostics contribute many of the educational competencies that provide a base upon which to build."**

The health, safety, and welfare of California consumers are being jeopardized as a result of the rapid growth of sleep medicine outstripping qualified practitioners. Without regulatory oversight, a growing number of unlicensed and unqualified personnel are providing an array of sleep-related diagnostic and therapeutic services to the consumers often under the supervision of equally unlicensed and unqualified persons in non-medical facilities such as hotels.

2. LIST ALL TITLES CURRENTLY USED BY CALIFORNIA PRACTITIONERS OF THIS OCCUPATION. ESTIMATE THE TOTAL NUMBER OF PRACTITIONERS NOW IN CALIFORNIA AND THE NUMBER USING EACH TITLE.

The RCB estimates there are approximately 689 “practitioners” in California as shown in the following table:

TABLE A. CALIFORNIA PRACTITIONERS BY TITLE AND NUMBER

Practitioner Type	No. Practicing in CA	%	Estimated number also holding a national sleep credential	%
Licensed Respiratory Care Practitioners (RCPs) These practitioners are licensed by the RCB.	207	30%	44	21%
Other “Licensed” Professionals These practitioners are primarily licensed nurses.	34	5%	7	21%
Unlicensed Personnel These practitioners consist of unlicensed electroneurodiagnostic technicians, college students, and other individuals.	448	65%	210	47%
Totals	**689**	**100%**	**261**	38%

The figures in Table A are based on:

- Percentages obtained from the 2003 "Salary, Demographic, and Educational Needs Survey Report" **(Appendix A)** conducted on behalf of the Association of Polysomnographic Technologists.
- Actual number of credentialed personnel. As of April 2005 there were 261 Registered Polysomnographic Technologists**.** Forty-four (44) of these Registered Polysomnographic Technologists were licensed **Respiratory Care Practitioners (RCPs)**.
- The number of estimated sleep facilities/programs in California (317) and the number of personnel working at each facility as reported in the RCB's Polysomnography survey **(Appendix B2).**

3. IDENTIFY EACH OCCUPATIONAL ASSOCIATION OR SIMILAR ORGANIZATION REPRESENTING CURRENT PRACTITIONERS IN CALIFORNIA, AND ESTIMATE ITS MEMBERSHIP. FOR EACH, LIST THE NAME OF ANY ASSOCIATED NATIONAL GROUP.

California Society for Respiratory Care (CSRC) – Profession Advocate
Estimated Membership: 3,000
1961 Main Street, Watsonville, CA 95076, (831) 763-2772, www.csrc.org

- **Associated National Group**
  American Association for Respiratory Care (AARC) – Research and Profession Advocate
  Estimated Membership: 35,000
  9425 N. MacArthur Blvd., Suite 100, Irving, TX 75063-4706, (972) 243-2272, www.aarc.org

4. ESTIMATE THE PERCENTAGE OF PRACTITIONERS WHO SUPPORT THIS REQUEST FOR REGULATION. DOCUMENT THE SOURCE OF THIS ESTIMATE.

Based on the limited information received in a polysomnography survey conducted by the RCB in 2004, the RCB is fairly certain 50% of the people in the profession would support regulation of polysomnography.

The RCB does not have scientific data affirming this figure but all of the respiratory care associations are supportive of regulation and many of the medical associations are supporting the need to ensure polysomnography is conducted in appropriate settings with qualified personnel under the supervision of either a physician or a medical director. On June 20, 2004 in Vail, Colorado, the **AARC's Board of Medical Advisors (BOMA)** unanimously adopted a motion "That BOMA support the future goal of state regulation of the occupation of polysomnography and those who provide said polysomnography services and related sleep studies." However, in March of 2005, the **American Academy of Sleep Medicine [AASM]** took issue with New York State's draft declaratory ruling that only RCPs could conduct polysomnography studies, stating "the AASM fully supports the independent profession of Polysomnographic Technology as they clearly have the education, training and proven expertise to be the body performing diagnostic and therapeutic services at sleep center and laboratories and should be recognized as such."

The polysomnography associations are opposed to any regulation, as is the California Thoracic Society at this time. The Association of Polysomnographic Technologists stated in a position paper that it is opposed to limited licensure because it threatens the autonomy of the Polysomnography profession, and is inconsistent with their goal of establishing Polysomnography as a separate and distinct allied health profession. However, a response to the RCB's 2004 Survey question 31 regarding performance of sleep studies by inexperienced personnel (untrained/uneducated) resulting in serious patient harm or even patient death indicated the following: "The APT does not support the practice of Polysomnographic Technology by personnel who are inexperienced, untrained, or uneducated working in the profession of Polysomnographic Technology or any other health care profession. The training of a polysomnographic technician is of prime importance and under no circumstance should it be unsupervised. AASM accredited sleep disorders centers require a board-certified sleep specialist (or designee) to train polysomnographic technicians, with training periods lasting six months to one year."

5. NAME THE APPLICANT GROUP REPRESENTING THE PRACTITIONERS IN THIS EFFORT TO SEEK REGULATION. HOW WAS THIS GROUP SELECTED TO REPRESENT PRACTITIONERS?

The **RCB** is seeking regulation of polysomnographic technologists. In 2001, the RCB noted its concern with the unlicensed practice of respiratory care in many areas, including Polysomnography, in its report to the **Joint Legislative Sunset Review Committee (JLSRC).** In response, the JLSRC included in its 2002 recommendations to support the RCB's effort to review the function and skill of currently unlicensed technicians and further study to determine the need for regulation of these technicians. As a result of the RCB's findings, it recommended moving forward to seek regulation of this profession that is intertwined with the practice of respiratory care.

6. ARE ALL PRACTITIONER GROUPS LISTED IN RESPONSE TO QUESTION 2 REPRESENTED IN THE ORGANIZATION SEEKING REGULATION? IF NOT, WHY NOT?

No. The RCB licenses RCPs. Its mandate is to "protect the public from the unauthorized and unqualified practice of respiratory care and from unprofessional conduct by persons licensed to practice respiratory care." [Reference B&P, §3701]

With this proposal, the RCB hopes to establish the polysomnography technician license that would encompass all of the groups listed in response to Question 2.

SECTION B: CONSUMER GROUP IDENTIFICATION

7. DO PRACTITIONERS TYPICALLY DEAL WITH A SPECIFIC CONSUMER POPULATION? ARE CLIENTS GENERALLY INDIVIDUALS OR ORGANIZATIONS? DOCUMENT.

Clients are individuals of all ages from infants to the elderly. The International Classification of Sleep Disorders has identified over 80 sleep disorders afflicting infants, children and adults. The most commonly tested disorders are sleep apnea, restless legs syndrome, narcolepsy, and insomnia. The RCB's 2004 survey indicates the largest percent of services are provided to adults over 40, however, services are also provided to children and young adults as shown in the following table:

TABLE B. CONSUMER POPULATION

Age Group	%
Newborn – 19 years old Less than 3 months old 2% 3 months – 2 years 3% 3 years – 12 years 4% 13 years – 19 years 4%	**13%**
20 years – 39 years	**15%**
40 years – 59 years	**40%**
60 years – 79 years	**26%**
80 years and older	**5%**

8. IDENTIFY ANY ADVOCACY GROUPS REPRESENTING CALIFORNIA CONSUMERS OF THIS SERVICE. LIST ALSO THE NAME OF APPLICABLE NATIONAL ADVOCACY GROUPS.

The RCB has been unable to identify any advocacy groups representing California consumers exclusively.

Mr. Dave Hargett, Chairman of the American Sleep Apnea Association **(ASAA)**, reports his association represents all sleep apnea patients in America which includes Californians. He indicated other national sleep advocate organizations are the Narcolepsy Network, Restless Legs Syndrome Foundation, National Sleep Foundation, and the American Insomnia Association but unfortunately the sleep patient consumer rarely gets involved with national organizations because there is still not enough awareness of sleep disorders and sleep medicine. It is his understanding there are ASAA support groups in California that are managed primarily by sleep center staff who work independently from the national association, but they are not state-based consumer advocate groups.

American Sleep Apnea Association (ASAA) – Sleep Apnea Patient Advocate
1424 K Street NW, Site 302, Washington DC 20005, (202) 293-3650, www.sleepapnea.org

9. IDENTIFY ANY CONSUMER POPULATIONS NOT NOW USING PRACTITIONER SERVICES LIKELY TO DO SO IF REGULATION IS APPROVED.

Regardless of whether the profession is regulated, the number of consumers using these services will rise as awareness grows.

In 2003, the National Sleep Foundation's poll found nearly two-thirds of American adults do not get the nightly eight hours of sleep recommended for good health and optimal performance. In a poll taken in 2004, the National Sleep Foundation discovered more than two-thirds of all children (69%), experience one or more sleep problems at least a few nights a week. The ASAA estimates nearly 18 million people have sleep apnea, but millions of these adults and children have no idea they have this problem. They suffer needlessly from a common and potentially life threatening medical disorder that can be treated. According to the National Sleep Foundation's Vice President James Walsh, "there is an epidemic of sleepiness in our society."

Sleep medicine today is a classic case of demand outstripping supply. Licensing and regulating polysomnographic technologists will permit the California consumer to feel confident that only the most qualified sleep technicians are providing polysomnography services in the appropriate settings.

10. DOES THE APPLICANT GROUP INCLUDE CONSUMER ADVOCATE REPRESENTATION? IF SO, DOCUMENT. IF NOT, WHY NOT?

Yes. The RCB is mandated is to "protect the public from the unauthorized and unqualified practice of respiratory care and from unprofessional conduct by persons licensed to practice respiratory care." [Reference B&P, §3701]

11. NAME ANY NON-APPLICANT GROUPS OPPOSED TO OR WITH AN INTEREST IN THE PROPOSED REGULATION. IF NONE, INDICATE EFFORTS MADE TO IDENTIFY THEM.

Organizations interested in this proposed regulation include:

California Society for Respiratory Care (CSRC) – Profession Advocate
1961 Main Street, Watsonville, CA 95076, (831) 763-2772, www.csrc.org

Affiliates

- **American Association for Respiratory Care (AARC)** – Research and Profession Advocate
  9425 N. MacArthur Blvd., Suite 100, Irving, TX 75063-4706, (972) 243-2272, www.aarc.org

- **National Board for Respiratory Care (NBRC)** – Credentialing Body
  8310 Nieman Road, Lenexa, KS 66214-1579, (913) 599-4200, www.nbrc.org

California Thoracic Society (CTS) – State Professional Physician Society
202 Fashion Lane, Suite 219, Tustin, CA 92780-3320 (714) 730-1944, www.thoracic.org/ca.html

Affiliates

- **American Thoracic Society (ATS)** - National Professional Physician Society
  61 Broadway, New York, NY 10006-2755, (212) 315-8600, www.thoracic.org

The following national organizations ***do not*** have California chapters:

Commission on Accreditation of Allied Health Education Programs (CAAHEP)
Education Accreditation Body
1361 Park Street, Clearwater, FL 33756, (727) 210-2350, www.caahep.org

Committee on Accreditation of Polysomnographic Technology (COA-PSG)
(under the umbrella of CAAHEP) American Academy of Sleep Medicine,
One Westbrook Corporate Center, Suite 920, Westchester, IL 60154 708-492-0930

Committee on Accreditation for Respiratory Care (CoARC)-Education Program Accreditation Body
(under the umbrella of CAAHEP)
1248 Harwood Road, Bedford, TX, 76021-4244, (817) 283-2835, www.coarc.com

American Academy of Sleep Medicine (AASM) – Sleep Disorder Programs Accrediting Body
One Westbrook Corporation Center, Suite 920, Westchester, IL 60154, (708) 492-0930
www.aasmnet.org

Association of Polysomnographic Technologists (APT) – Profession Advocate
One Westbrook Corporate Center, Suite 920, Westchester IL, 60154, (708) 492-0796,
www.aptweb.org

Sleep Research Society (SRS) – Sleep/Medical Research
One Westbrook Corporation Center, Suite 920, Westchester, IL 60154, (708) 492-1093
www.sleepresearchsociety.org

Board of Registered Polysomnographic Technologists (BRPT) – Credentialing Body
8201 Greensboro Drive, Suite 300, McLean, VA 22102, (703) 610-9020, www.brpt.org

American Society of Electroneurodiagnostic Technologists (ASET) – Research and Profession Advocate, 6501 East Commerce Avenue, Suite 120, Kansas City, MO 64120, (816) 931-1120,
www.aset.org

American Sleep Apnea Association (ASAA) – Sleep Apnea Patient Advocate
1424 K Street NW, Site 302, Washington DC 20005, (202) 293-3650, www.sleepapnea.org

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
Health Care Organization Accrediting Body
One Renaissance Blvd., Terrace, IL 60181, (630) 792-5000, www.jointcommission.org

Opposition

The Association of Polysomnographic Technologists **(APT)** is the profession advocate for credentialed polysomnographic technologists. The APT has established four position papers opposing regulation in connection with respiratory care licensure **(Appendix C)** and has publicly advocated for exemption from respiratory care practice acts. Their argument is that the diagnostic utility of polysomnography depends on the ability to correlate specific changes or abnormalities of one physiological parameter rather than independent measurements of each variable, such as respiratory function, within the parameter. However, respiratory function is noted as being the most common disturbance and treatment available to be tested via sleep evaluation. While the APT recognizes many functions are considered respiratory care, it believes respiratory care boards who bar the limited practice of respiratory care by polysomnographic technologists, are limiting the "availability, safety and quality of [Polysomnography] monitoring, diagnostic and therapeutic services to patients." The APT also states it is opposed to limited licensure because it threatens the autonomy of the Polysomnography profession, and is inconsistent with their goal of establishing Polysomnography as a separate and distinct allied health profession. To date, the RCB has not received any written opposition from APT regarding the proposal to regulate polysomnographic technologists.

The American Academy of Sleep Medicine (AASM), a sleep disorder programs accrediting body, has attended various meetings with subject matter related to the regulation of polysomnographic technologists and voiced opposition to regulation of the field at this time. To date, no written opposition has been received by the RCB.

The California Thoracic Society (CTS), a state professional physician society affiliated with the American Lung Association, has been very active in the RCB's review of polysomnography. The CTS has expressed opposition to regulating, in any manner, the practice of polysomnography. The CTS has conveyed the supervising physician or medical director should have direct responsibility of personnel.

On November 24, 2004, the CTS provided the RCB with its position paper **(Appendix D)**. While the RCB agrees with CTS's position that the supervising physician or medical director should have direct responsibility of personnel, there is no mechanism in place to ensure all physicians are providing the necessary oversight, testing competency, requiring criminal background checks and applying the uniform standards established for sleep medicine.

SECTION C1: SUNRISE CRITERIA

I. UNREGULATED PRACTICE OF THIS OCCUPATION WILL HARM OR ENDANGER THE PUBLIC HEALTH SAFETY AND WELFARE

12. IS THERE OR HAS THERE BEEN SIGNIFICANT PUBLIC DEMAND FOR A REGULATORY STANDARD? DOCUMENT. IF NOT, WHAT IS THE BASIS FOR THIS APPLICATION?

In 1999, the American College of Chest Physicians indicated in an article entitled *"Conundrums in Sleep Medicine,"* published in its Chest magazine, that some form of regulatory control for sleep labs and personnel should be in place.

The American Association of Respiratory Care **(AARC)** finds polysomnography to be a "sub-specialty" of respiratory care and recognizes that by virtue of their license, respiratory therapists are performing sleep studies today and have been involved in this field since its inception.

In April 2003, the Committee on the Accreditation of Allied Health Education Programs unanimously approved the Committee on Accreditation for Respiratory Care's Standards and Guidelines for the Respiratory Care Profession which allows respiratory care programs to seek accreditation of a polysomnography certificate of completion option as an "add-on" to their existing programs.

In June of 2004, the Board of Medical Advisors (BOMA) unanimously supported a motion **"to support the future goal of state regulation of the occupation of polysomnography and those who provide said polysomnography services and related sleep studies."** The BOMA is comprised of physicians representing various medical organizations which include the following:

- American Thoracic Society (ATS);
- American College of Chest Physicians (ACCP);
- American Society of Anesthesiologists (ASA);
- American Academy of Pediatrics (AAP);
- American College of Allergy, Asthma and Immunology (ACAAI);
- Society of Critical Care Medicine (SCCM), and
- The National Association for Medical Direction of Respiratory Care (NAMDR).

In the summer of 2004, the RCB developed three surveys related to the practices of polysomnography, pulmonary function testing and hyperbaric oxygen therapy. The RCB issued notices to 1,545 organizations and persons holding an interest in one or more of these professions and encouraging input via surveys available on the RCB's website. Hard copies were also mailed to 200 of these various organizations and persons.

Approximately 491 of the organizations notified are directly associated with the practice of polysomnography. Notices were sent to credentialed polysomnographic technologists, accredited sleep centers, sleep centers found on the internet, sleep associations, and sleep disorder patient

advocacy groups. In addition, hard copies of the survey were sent to 67 organizations/persons affiliated with polysomnography. Twenty-nine (29) surveys were returned to the RCB (the tabulation of all responses are included in **Appendix B**).

The majority of respondents to the RCB's polysomnography survey indicated support for some form of regulation of this field. Most indicated regulation of sleep technicians would strengthen confidence in sleep study services by decreasing the potential for patient harm through education, training and criminal background checks. The responses also indicated regulation would provide physicians with more viable resources. An overwhelming majority believe that educational programs would evolve if the profession was regulated*.*

Currently, the National Board for Respiratory Care, which is a voluntary health certifying board created in 1960 to evaluate the professional competence of respiratory therapists, is moving toward the development of a specialty certification in polysomnography for credentialed respiratory therapists. Since its inception, the National Board for Respiratory Care has issued over 250,000 professional credentials to more than 150,000 individuals and currently tests nearly 15,000 candidates annually.

13. WHAT IS THE NATURE AND SEVERITY OF THE HARM? DOCUMENT THE PHYSICAL, SOCIAL, INTELLECTUAL, FINANCIAL OR OTHER CONSEQUENCES TO THE CONSUMER RESULTING FROM INCOMPETENT PRACTICE.

As with respiratory therapy, knowledge of normal cardiorespiratory, neurological and sleep physiology is required and provides the basis for monitoring polysomnograms and recognizing pathologic processes.

Risks are increased when unqualified personnel oversee polysomnographic studies because they lack the knowledge foundation, education, training, and experience to make accurate assessments and evaluations as it relates to equipment operation or calibration, patient responses, and contraindications.

Inability to recognize hazards and be aware of and properly use intervention methods could lead to permanent injury to the patient, even death. Inaccurate test results can lead to the improper diagnosis and treatment jeopardizing patient safety and resulting in unnecessary expenditures.
The incompetent practice of polysomnography can subject patients to skin irritations, lung over-distension, gastric insufflation and abdominal distension causing aspiration, pressure sores, electrical shock and burns, eye injuries, vocal cord paralysis, bronchospasm, laryngospasm, dental accidents, bleeding, mouth and tongue ulceration, tracheal damage, pneumonia, hypotension and hypoventilation. This listing is not inclusive of all the hazards facing patients of polysomnography. The American Association for Respiratory Care (AARC) provides several Clinical Guidelines **(Appendix E)** which provide in part, complications and hazards associated with polysomnography.

Inaccurate test results can lead to the improper diagnosis and treatment of sleep disorders, thereby jeopardizing patient safety. For example, failure to properly diagnosis and treat sleep apnea, a serious, potentially life-threatening condition, could result in death or severe injury from automobile accidents, heart attacks, strokes or during surgical procedures. The National Commission on Sleep Disorders estimates 38,000 cardiovascular deaths due to sleep apnea occur annually. Although not necessarily attributed to sleep apnea, the National Highway Traffic Safety Administration attributes driver fatigue for over 100,000 automobile accidents annually which resulted in 1,550 dead and 71,000 injured.

The California consumer is also impacted financially. The Sleep Disorder Center of Virginia reports sleep-related accidents cost as much as $46 billion annually. Further, inaccurate testing and misdiagnoses can result in unnecessary expenditures to patients and insurance companies through the need to retest the patient or the procurement of inappropriate or inadequate sleep equipment.

14. HOW LIKELY IS IT THAT HARM WILL OCCUR? CITE CASES OR INSTANCES OF CONSUMER INJURY. IF NONE, HOW IS HARM CURRENTLY AVOIDED?

The majority of responses (75%) to the RCB's 2004 survey indicated that if polysomnography was performed by inexperienced (uneducated and untrained) personnel it could result in serious patient harm or even patient death.

Respondents to the survey also indicated a patient's personal rights could be violated or well being jeopardized if a polysomnographic technician has a criminal background in any of the following areas; fraud/theft, substance abuse (alcohol and/or drug), battery, and (the highest ranking fear) sexual misconduct.

Polysomnography is generally performed during an "overnight stay" or throughout a significant period of the day. The patient is placed in a vulnerable position in that he/she is sleeping during the study. Sleep technicians place electrodes and other monitoring equipment on a patient's head, chest, waist and/or legs, making adjustments as necessary. Bed restraints may also be necessary depending on the situation. Sleeping disorders may cause paralysis or disorientation upon wakening. There is a sleep sex disorder which includes sleep activities from disruptive moaning to rape-like behavior toward bed partners without memory of the events. Although complaints of sexual misconduct upon the part of the technologists have been made, as yet no evidence has substantiated the complaints. Lately many sleep studies are being performed in non-medical facilities such as hotel rooms or patient homes with questionable supervision.

The RCB found three cases of patient harm involving an electroencephalography technician, a laboratory technician, and a nurse, professions which also perform polysomnography studies.

The electroencephalography technician was convicted of three counts of lewd and lascivious conduct and two counts of perjury (Vermont v. Nicholas Tonzola – 159 VT. 491, 497, 621 A.2d 243, 246 1993). In September 2004, in California, a laboratory technician, Dante Arnaud, 37, of Santa Ana was arrested for sexual battery and sexual penetration by a foreign object. Arnaud allegedly came into at least seven women's rooms in the maternity ward at Garden Grove Hospital and Medical Center, on the pretense of drawing blood samples and conducting breast and vaginal examinations. In the Enright v. Inspector General (1991.06.19 DAB CR138) case, Enright, a nurse and also a certified laboratory technician, was terminated for his unprofessional conduct (inappropriately touching male patients). The Court found that Enright broke a high duty of care and trust because a hospital patient may be completely helpless and totally dependent on the professional care of the hospital staff. The Court found patients need to believe that when hospital personnel touch their bodies, it is for professional reason, not to gratify the sexual desire of the hospital staff. Further, the Court found trustworthiness to work with patients is the same whether the functions are as a nurse or as a laboratory technician. Given these examples of events occurring in hospital settings, the RCB is gravely concerned about what can happen in sleep facilities located inside of hospitals and facilities and hotel rooms outside of hospitals.

Lack of regulation places the patient at risk because criminal background checks are not conducted on unlicensed personnel. The RCB's 2004 survey indicated 57% of sleep facilities do not perform criminal background checks. Seventy-five percent (75%) of the stand-alone facilities, physician offices, hotels and home care settings are not performing criminal background checks.

The United States Food and Drug Administration reports events associated with medical equipment on their Manufacturer and User Facility Device Experience (MAUDE) Database. The following four incidents involving polysomnography were listed on the database. Details can be found in **Appendix F.**

1. Patient Suffers Abdomen Burns

"A patient suffered burns on his abdomen during a sleep study procedure. Strain gauge leads were plugged into the battery test receptacle instead of the abdominal outlets of a dc converter box, which caused the strain gauge to heat up. The patient's surgery had to be postponed due to the burn. The incident was the result of user error on the part of the technician."

2. Patient Sent to Emergency Room - Respiratory Distress

This report indicates a sleep study patient experienced a rise in PACO2, which the sleep facility alleged resulted from use of a specific piece of equipment. Patient had **Chronic Obstructive Pulmonary Disease (COPD)** and known high baseline CO2. Patient was sent to the emergency room, placed on **bi-level positive pressure (BIPAP)** therapy and CO2 levels dropped.

The device was returned and found to meet all operating specifications. "Further conversation with the sleep facility has led to the conclusion that the patient condition, along with titration and use of oxygen in the sleep lab, contributed to a reduction in the patient's respiratory drive to a level that required hospitalization. There was no malfunction of the device. "

3. Patient Sent to Emergency Room – Mask Burn/Pressure Necrosis

"Patient had cracked and peeling skin on both sides of the nose and staining on the area around the lips and nose where a gold seal mask [Continuous Positive Airway Pressure **(CPAP)** mask] came in contact with the skin. The patient could smell a chemical and had a burning/stinging sensation. Patient was sent to the emergency room where they diagnosed pressure necrosis (the localized death of living cells as from infection or the interruption of blood supply) because of the coloring on the face….This facility is using cidex opa solution to disinfect cpap (sleep lab) masks.

The bottle label for cidex opa includes in the warning section a note to 'avoid contact with eyes, skin or clothing. Direct contact with skin may cause temporary staining.'….Proper rinsing of instruments after disinfecting with cidex opa should eliminate the potential for patient contact. Rinsing is detailed in the…..directions for use section and is very specific regarding volumes of water, duration of rinsing and recommends repeated rinsing."

4. Patient Sustains First Degree Chemical Burn

This report indicates a patient undergoing a sleep study sustained a first degree chemical burn on his/her face from a CPAP mask also disinfected with cidex opa. It was determined through discussions between the manufacturer and cidex opa and the risk management department at the sleep facility that the cleaning and disinfection instructions for cidex opa solution were not followed by the facility.

5. Anesthesia Complications Related to Obstructive Sleep Apnea

Patients with sleep apnea require special precautions and measures to ensure safe anesthetic care which may include awake intubation, postoperative intubation and mechanical ventilation, tracheostomy (if other attempts to manage the airway are unsuccessful), and vigil monitoring for apnea events post surgery. Anesthesiologists have noted patients have been misdiagnosed as not having obstructive sleep apnea, despite precautionary sleep studies, leading to complications during surgery.

15. WHAT PROVISIONS OF THE PROPOSED REGULATION WOULD PRECLUDE CONSUMER INJURY?

The RCB believes strongly only qualified and competent personnel should be performing polysomnography studies on California consumers under the supervision of qualified and competent physicians or medical directors in safe settings.

Regulation of polysomnographic technologists would enable the RCB to ensure applicants for licensure meet education and training standards established for polysomnography by examining for competency prior to licensure, thereby reducing the risk of consumer injury.

Regulation would also permit the RCB to ensure sleep studies are conducted only in appropriate and safe settings under the supervision of qualified physicians and medical directors, thereby reducing the risk of consumer injury.

Regulation of the profession would enable the RCB to conduct criminal background checks on polysomnographic technologists prior to licensure, thereby reducing the risk of harm to the consumer.

Regulation of the profession would also permit the RCB to enforce the provisions of the regulations to meet its mandate to protect and serve the California consumer.

II. EXISTING PROTECTIONS AVAILABLE TO THE CONSUMER ARE INSUFFICIENT

16. TO WHAT EXTENT DO CONSUMERS CURRENTLY CONTROL THEIR EXPOSURE TO RISK? HOW DO CLIENTS LOCATE AND SELECT PRACTITIONERS?

Polysomnography is being conducted in acute-care hospitals and independent facilities ***as well as in hotel rooms and patients' homes***. Consumers who are referred by their physicians to accredited sleep disorder facilities reduce their exposure to risk. Although the personnel may not be credentialed in polysomnography nor had criminal background checks, the likelihood of problems is reduced because the level of supervision is presumably either a physician or medical director and presumably the facility's protocols and procedures are well established. However, the quality and standard of care of each sleep program can not be determined except for the small percentage of sleep programs that hold accreditation which is not required by the State or by most, if any, insurance carriers for reimbursement. Without regulation there is no oversight of sleep laboratories or unlicensed sleep personnel and both continue to expand.

Consumers may be referred to practitioners by their physician. They may locate practitioners through the yellow pages, word of mouth, or the internet. The performance of sleep studies in hotel rooms is being promoted on the internet and is up for debate as to whether this practice is professional or unscrupulous.

It is believed sleep laboratories are opening regularly because there are no requirements for the set-up or operation of facilities, there is a consumer demand for sleep testing, and there is significant income to be gained by practitioners from the consumer. In addition to the company that will "sell" physician and polysmnographer services and assist one in establish a sleep lab (as noted on page 2), there are others who are using hotel chains as their laboratory sites.

A company named Sleepwell Diagnostic Center provides investor updates through an internet site [www.sleeptest.com] where it is reporting numerous sleep centers opening nation-wide ***in hotels***. A 2004 article in the Salt Lake Tribune written by Carey Hamilton states "David Kay, the founder of **California-based** Sleepwell, came up with the idea of putting a sleep center in a hotel after his doctor sent him to a California sleep center in an office building in a "terrible location." Sleep testing in hotel rooms has also been reported to the RCB in a less favorable light citing "unlicensed technicians with three days training in polysomnography are administering CPAP and BIPAP to many California sleep study consumers."

Home sleep studies are also a popular choice by sleep disorder programs citing familiar surroundings are conductive to obtaining accurate sleep measures. Home sleep studies may be attended or not attended by sleep study personnel. There remains a division among the sleep community profession as to whether home sleep studies are as effective as studies performed in a laboratory, with strong arguments on both sides.

The American Academy of Sleep Medicine **(AASM)** and Joint Commission on Accreditation of Healthcare Organizations **(JCAHO)** have accreditation processes for sleep programs. The AASM offers voluntary accreditation for sleep disorder programs and has designed standards for accreditation for laboratories evaluating only sleep-related breathing disorders as well as full-service programs. Some sleep programs also provide polysomnographic evaluations of infant apnea and other pediatric sleep disorders, and REM-related nocturnal penile tumescense studies, although these are not required for accreditation [reference: http://www.aasmnet.org/centervslab.asp]. The AASM reports, as of October 2004, it has accredited a total of 604 sleep programs in the United States. California represents 7.1% of this figure.

As of October 2004, there are 43 sleep programs located in California accredited by the AASM and 11 by the JCAHO. Based on the number of these accredited facilities and internet listings, it is estimated there are a minimum of 175 sleep laboratories or companies, of which only 54 hold accreditation, providing polysomnography services to the California consumer.

In addition to sleep disorder testing being conducted in facilities, hotels and homes, it is also being conducted in physician offices. As of October 2004, there are 193 physicians accredited in sleep medicine by the American Board of Sleep Medicine. Yet it is believed by the RCB that this figure only represents half (or even less) of the physicians actually practicing sleep medicine for a total estimate of 386 practicing physicians.

17. ARE CLIENTS FREQUENTLY REFERRED TO PRACTITIONERS FOR SERVICES? GIVE EXAMPLES OF REFERRAL PATTERNS.

Yes, from the limited responses received to the RCB's 2004 Survey, it appears the majority of referrals are made by healthcare practitioners, 88% come from physicians and 4% are made by RCPs, nurse practitioners and registered nurses. Eight percent (8%) are self referrals; consumers who "walk-in" to have a sleep study performed.

Again, based on the information provided in Question 16 and without regulatory authority, the RCB is unable to determine referral frequency and patterns. However, it is anticipated unscrupulous and unethical physicians may be referring patients to hotel or office facilities in which they have vested interests. Further, physicians who are not knowledgeable in polysomnography standards may honesty believe that sleep studies performed in the "home" or "hotel rooms" are "standard" and that accreditation of sleep facilities does not exist or is not beneficial. The RCB understands the profession is split on whether the" home" is a suitable location. There are a number of physicians who are well versed in polysomnography who would state the "home" ***is*** the best place to perform a sleep study.

18. ARE CLIENTS FREQUENTLY REFERRED ELSEWHERE BY PRACTITIONERS? GIVE EXAMPLES OF REFERRAL PATTERNS.

No. Practitioners do not refer patients anywhere else.

19. WHAT SOURCES EXIST TO INFORM CONSUMERS OF THE RISK INHERENT IN INCOMPETENT PRACTICE AND OF WHAT PRACTITIONER BEHAVIORS CONSTITUTE COMPETENT PERFORMANCE?

There is information available on the risks inherent in incompetent practice and what constitutes competent performance through the many medical organizations and association. For example, the Association of Polysomnographic Technologists **(APT)** has developed core competencies (as documented in Question 43) that clearly address inherent risks, competent practice and appropriate facilities. However, most consumers would not know where to locate this information. Regulation of the profession would enable the RCB to educate the public on competence and incompetent performance.

20. WHAT ADMINISTRATIVE OR LEGAL REMEDIES ARE CURRENTLY AVAILABLE TO REDRESS CONSUMER INJURY AND ABUSE IN THIS FIELD?

Without regulatory authority, the RCB can only guess the current administrative or legal remedies for consumers injured or abused in polysomnography studies is through hospital patient rights protocols, insurance company complaints, local law enforcement authorities and lawsuits. The RCB understands the Board of Registered Polysomnographic Technologists **(BRPT)** has a Judiciary Committee that investigates complaints filed against credentialed polysomnographic technologists.

21. ARE THE CURRENTLY AVAILABLE REMEDIES INSUFFICIENT OR INEFFECTIVE? IF SO, EXPLAIN WHY.

The RCB believes currently available remedies are insufficient and ineffective. As outlined in Question 16, many sleep studies are being performed in places other than accredited hospital facilities by unqualified personnel. This factor leaves the consumer who is seeking remedy for injury or abuse filing complaints with their insurance company (if they have one) and/or with the local authorities who may or may not have the staff to adequately investigate and take legal action. Filing lawsuits is also another avenue open to the consumer, however lawsuits are costly and time consuming with questionable outcome. Filing a complaint with the BRPT Judiciary Committee may result in a credentialed and trained polysomnographic technologist being disciplined, but this does not address the countless other sleep personnel who are not credentialed.

Regulation of the profession would enable the RCB to be proactive by checking criminal backgrounds prior to practice, establish appropriate supervision guidelines and required competency levels and to investigate complaints and seek redress on behalf of the California consumer.

III. NO ALTERNATIVES TO REGULATION WILL ADEQUATELY PROTECT THE PUBLIC

22. EXPLAIN WHY MARKETPLACE FACTORS WILL NOT BE AS EFFECTIVE AS GOVERNMENTAL REGULATION IN ENSURING PUBLIC WELFARE. DOCUMENT SPECIFIC INSTANCES IN WHICH MARKET CONTROLS HAVE BROKEN DOWN OR PROVEN INEFFECTIVE IN ASSURING CONSUMER PROTECTION.

Although minimal competency, education and training standards have been established by the profession, the professional organizations have no enforcement authority to ensure these standards are being followed other than the BRPT can revoke a *voluntary* credential it granted.

Without a regulatory body, consumers have no central location in which to seek remedy for problems they may encounter with polysomnography practitioners. Although the RCB has no "specific instances" to document it can anticipate situations will occur in this profession which are similar to those occurring in other healthcare professions. For example, consumers who have been misdiagnosed by practitioners may not be aware of the harm until they are later properly treated. They may not want to try, or even know how, to track down an unlicensed person and sue because of the cost and unlikely outcome. Consumers may not want to or be able to afford to hire an attorney who would sue a physician because of a bad referral with resulting harm. According to a business law instructor, malpractice cases are difficult to win in California and it is hard to find attorneys who will take a case unless there is significant injury and direct responsibility.

Without a regulatory body, consumers are not protected from incompetent practitioners who they may not recognize as incompetent. For example, if a consumer is misdiagnosed as NOT having sleep apnea and ends up in a car wreck he or she is not likely to blame the sleep lab even though it is likely the results were not reliable because the polysomnography operator was incompetent. If a misdiagnosed sleep apnea patient undergoes anesthesia and has serious complications but is recovered by the anesthesiologist, he or she will not likely recognize the complications were brought

on by the misdiagnosis. The anesthesiologist may recognize what happened, but he or she is not going to file criminal or civil charges. The anesthesiologist might inform the sleep study lab that their failure to properly diagnose almost caused him to lose a patient but the consumer will never know.

23. ARE THERE OTHER STATES IN WHICH THIS OCCUPATION IS REGULATED? IF SO, IDENTIFY THE STATES AND INDICATE THE MANNER IN WHICH CONSUMER PROTECTION IS ENSURED IN THOSE STATES. PROVIDE, AS AN APPENDIX, COPIES OF THE REGULATORY PROVISIONS FROM THESE STATES.

The following table (Table C) includes a listing of states that have addressed the issue of polysomnography through:

- inclusion of polysomnography into respiratory care practice acts,
- varying exemptions to respiratory practice acts,
- establishment of Polysomnography Licensing Boards, or
- declarations or position statements.

The exemptions vary in that Alabama exempts any individual employed as a polysomnographic technologist working in a sleep center or diagnostic sleep clinic while Colorado limits the scope of practice for a registered polysomnographic technologist. Vermont's exemption requires the supervising physician to be trained in sleep medicine. Most exemptions however require 1) supervision by a licensed physician, 2) personnel to be credentialed as a polysomnographic technologists, and 3) performance in accredited sleep centers. Idaho, North Dakota and Wyoming incorporated polysomnography into their respiratory care practice acts.

According to Barbara Zittel, Ph.D., the executive secretary of New York State Board for Respiratory Therapy, New York issued a draft declaratory ruling requiring licensure as a RCP to perform polysomnography in November of 2004 which was disseminated to a number of facilities and agencies. She writes that "legislators throughout NY voiced a concern that voters in their areas would not be able to receive poly-services if the policy were [sic] enforced. After discussions we were able to get their buy-in on legislation that would address this issued by creating a Polysomnography Committee. The legislators agreed that if the legislation is not passed soon the letter would be changed from a draft to final." Dr. Zittel anticipates the proposed legislation will pass next legislative session. The draft declaratory position can be found in **Appendix G54.**

New Jersey and Louisiana established polysomnographic practice acts and Maryland established a polysomnography standards committee within its State Board of Physicians.

Although the states vary in how they are addressing this new profession, it is obvious they share California's concerns that too many sleep studies are being performed by unqualified staff in questionable settings with questionable supervision.

TABLE C. POLYSOMNOGRAPHY AS REGULATED IN OTHER STATES

State	EXEMPTED from Respiratory Practice Act		RPGST Personnel INCLUDED in Respiratory Practice Act	ENACTED RPGST Licensing Board or Committee		Declaration or Position Statement	Appendix
	Medical Supervision Required	No Require-ments		Exempts RCPs	Does NOT Exempt RCPS		
Alabama		2004					G1
Colorado	2006						G3
Florida		limited					G6
Idaho			2003				G9
Illinois	2006						G12
Iowa	2002						G14
Louisiana				2005			G15
Maryland					2006		G21
Nebraska	2004						G39
New Jersey					2005		G41
New Hampshire	2003						G53
New York						2004	G54
North Carolina						2005	G55
North Dakota			2006				G64
Ohio	2000						G71
South Carolina						2005	G73
Utah	2006						G74
Wyoming			2003				G78
Vermont	2003						G83

24. WHAT MEANS OTHER THAN GOVERNMENTAL REGULATION HAVE BEEN EMPLOYED IN CALIFORNIA TO ENSURE CONSUMER HEALTH AND SAFETY? SHOW WHY THE FOLLOWING WOULD BE INADEQUATE:

- **A. CODE OF ETHICS**
- **B. CODES OF PRACTICE ENFORCED BY PROFESSIONAL ASSOCIATIONS**
- **C. DISPUTE-RESOLUTION MECHANISMS SUCH AS MEDIATION OR ARBITRATION**
- **D. RECOURSE TO CURRENT APPLICABLE LAW**
- **E. REGULATION OF THOSE WHO EMPLOY OR SUPERVISE PRACTITIONERS**
- **F. OTHER MEASURES ATTEMPTED**

There is currently no means by which to ensure the consumer's health and safety other than for the RCB to begin enforcing the unlicensed practice of respiratory care. As stated in Question 1, this is a relatively new field and encompasses knowledge and technology from other fields of medicine, in addition to respiratory and pulmonary care. Because of this, the RCB opted to delay enforcement action for the unlicensed practice of respiratory care pending further exploration of this emerging field to determine the best method to serve and protect California consumers.

A code of ethics only serves to assist ethical individuals in determining the appropriate course to follow. It cannot protect the unsuspecting consumer from unethical practitioners.

Codes of practices enforced by professional associations address only those individuals who want to maintain their professional status in these organizations. Other than personal censor there is little else the professional associations can do to protect the consumer. The exception is the Board of Registered Polysomnographic Technologists (BRPT) who, the RCB understands, will investigate and revoke credentials if warranted. This, however, only applies to those individuals who possess the voluntary credential, not the countless numbers who do not.

While dispute resolution mechanisms may exist to resolve the consumer complaints within hospital settings and insurance companies there are no mechanisms which can ensure the consumer's health and safety during sleep studies.

Consumers can contact local authorities if they have been harmed and seek restitution through the court system. However, this will not prevent them from being harmed by uneducated and untrained sleep personnel during sleep studies. Regulation will not remove all potential harm but it would reduce that potential by ensuring only educated and competent personnel perform sleep studies in appropriate and supervised settings.

Physicians and medical directors are currently regulated by California and the hospitals in which they practice. However, sleep studies are now being performed in hotels and offices. Without regulation, there is no way to ensure the individuals performing sleep studies in these facilities are being supervised by individuals who are already regulated.

The RCB is not aware of any other measures being attempted.

25. IF A "GRANDFATHER" CLAUSE (IN WHICH CURRENT PRACTITIONERS ARE EXEMPTED FROM COMPLIANCE WITH PROPOSED ENTRY STANDARDS) HAS BEEN INCLUDED IN THE REGULATION PROPOSED BY THE APPLICANT GROUP, HOW IS THAT CLAUSE JUSTIFIED? WHAT SAFEGUARDS WILL BE PROVIDED CONSUMERS REGARDING THIS GROUP?

The RCB would allow those applicants for licensure who have the "paid work experience" as noted in number 5 listed below to be grandfathered into the profession. The RCB would accept work experience received up to 24 months prior to enactment of a licensure law. However, applicants would still be required to meet requirements 6 through 11 listed below.

Requirements for licensure are:

1. Current licensure as a California RCP **OR**
2. Graduation from an accredited respiratory care program **OR**
3. Graduation from an accredited electroneurodiagnostics program **OR**
4. Graduation from a polysomnography educational program approved by the RCB **OR**
5. 18 months (3000 hours) of full-time paid work experience as a "polysomnographic technologist applicant" including 1000 hours in "polysomnography related respiratory care services"

AND

6. Successful completion of the BRPT or NBRC polysomnography examinations **AND**
7. High School Graduate or its equivalent **AND**
8. 18 years or older **AND**
9. Current CPR certificate **AND**
10. Criminal Background Clearance **AND**
11. Any other educational courses, clinical practice or work experience identified by the RCB through regulation.

Consumer safety is protected by the examination and criminal background clearance.

IV. REGULATION WILL MITIGATE EXISTING PROBLEMS

26. WHAT SPECIFIC BENEFITS WILL THE PUBLIC REALIZE IF THIS OCCUPATION IS REGULATED? INDICATE CLEARLY HOW THE PROPOSED REGULATION WILL CORRECT OR PRECLUDE CONSUMER INJURY. DO THESE BENEFITS GO BEYOND FREEDOM FROM HARM? IF SO, IN WHAT WAY?

Regulation of polysomnography personnel will ensure the public is protected from unscrupulous, incompetent and unethical practitioners. Regulation would permit the RCB to ensure applicants for licensure meet the standards of the profession in education and training. It would permit the RCB to examine the applicant's knowledge, skills and abilities thereby ensuring the public that the practitioner

is competent to provide polysomnography services in a safe and effective manner. Responses to the RCB's 2004 Survey indicated that 46% of individuals undergoing sleep studies had to be retested because personnel failed to perform a test or treatment correctly or failed to ensure the equipment was calibrated properly (see question 29 of **Appendix B7)**. Regulation of the profession would permit the RCB to conduct criminal background checks thereby protecting the consumer from individuals who may harm them by theft, sexual misconduct, battery or incompetence due to substance abuse. Regulation of the profession would ensure polysomnography studies were performed by qualified staff and supervision. Regulation of the profession would provide the public an avenue to seek remedy for incompetent or abusive behavior. Regulation of the profession would provide the public with the assurance that the RCB would discipline or revoke the licenses of those individuals who harm the public or fail to comply with the profession's standards.

These benefits do not go beyond freedom from harm, but they do provide the consumer with better protections than currently exist.

27. WHICH CONSUMERS OF PRACTITIONER SERVICES ARE MOST IN NEED OF PROTECTION? WHICH REQUIRE LEAST PROTECTION? WHICH CONSUMERS WILL BENEFIT MOST AND LEAST FROM REGULATION?

All California consumers are in need of protection from the unqualified and incompetent practice of polysomnography regardless of age or circumstances. Infants, young children, and teenagers however, may be at a greater risk if parents leave their children at sleep study laboratories under the assumption that the personnel are "licensed" or possess the safeguards that licensed professionals have such as competency and criminal background clearance.

28. PROVIDE EVIDENCE OF "NET" BENEFITS WHEN THE FOLLOWING POSSIBLE EFFECTS OF REGULATION ARE CONSIDERED:

- **A. RESTRICTION OF OPPORTUNITY TO PRACTICE**
- **B. RESTRICTED SUPPLY OF PRACTITIONERS**
- **C. INCREASED COSTS OF SERVICE TO CONSUMER**
- **D. INCREASED GOVERNMENTAL INTERVENTION IN THE MARKETPLACE.**

The proposed regulation of polysomnographic personnel would not restrict opportunities to practice or the supply of practitioners. As one responder to the RCB's 2004 Survey states, "there is a high demand [for] and shortage of these personnel." Medicare and MediCal already cover these services, although the survey indicated most responders believe the reimbursement should be greater and that some individuals are not seeking the polysomnography service because of the current reimbursement rate.

Survey question 6 asked if responders believed regulation would increase the cost of services. The responses varied from 37% answering "yes," 27% saying "no," and the remaining 36% were unsure if the cost would increase the cost of services.

The net benefit of increased governmental intervention in the marketplace is as stated in Question 26 above. In addition, regulation would bring about more awareness of sleep disorders, providing relief to many more of the millions of Americans who currently suffer from sleep disturbances (according to the National Sleep Foundation - see question 9 of sunrise report) .

Further, there will be a greater demand for and availability of educational programs. The majority of respondents to the RCB's survey question 35 which asked if they believed the proposed regulation would bring about more education and training programs answered in the affirmative. One respondent stated, "I hope it would improve the quality and length of existing educational programs, as well as encourage the growth of new ones. There are numerous educational opportunities available for individuals who wish to enter the field. Unfortunately, most are of very limited duration (2 weeks or less) and have very limited opportunity for supervised clinical practice. I believe that it's essential that formal, structured educational and training programs be established." Another respondent indicated, "Increased educational/training programs are more prevalent because of the Association of Polysomnographic Technologists **(APT)** focus on establishing standards for the training of polysomnographic technicians, not because of practice regulation. The APT is dedicated to educating polysomnographic technologists. The Standards and Guidelines for the Education of Polysomnographic Technologists were adopted by the Committee on Accreditation of Polysomnographic Technology and approved by the Commission on Accreditation of Allied Health Education Programs in April 2004. Currently, programs in community colleges are using these standards as they begin to build and expand their educational opportunities for the future. The APT has developed a standardized curriculum outline specific to polysomnographic technology that will be useful to interested colleges."

Although the above mentioned individual believes increased educational and training programs are more prevalent because of the APT rather than governmental intervention, regulation of the profession would permit the RCB to ensure applicants for licensure **meet the standards** of the profession in education and training. It would also permit the RCB to examine applicant knowledge, skills and abilities to ensure the practitioner **is competent** to provide polysomnography services in a safe and effective manner.

V. PRACTITIONERS OPERATE INDEPENDENTLY MAKING DECISIONS OF CONSEQUENCE

29. TO WHAT EXTENT DO INDIVIDUAL PRACTITIONERS MAKE PROFESSIONAL JUDGMENTS OF CONSEQUENCE? WHAT ARE THESE JUDGMENTS? HOW FREQUENTLY DO THEY OCCUR? WHAT ARE THE CONSEQUENCES? DOCUMENT.

Polysomnography personnel make professional judgments of consequence in all sleep studies particularly those involving CPAP and BIPAP procedures for sleep apnea. They need to know when to stop the procedure, when the patient is not tolerating the procedure, when cardiac complications are occurring and when to contact the physician or medical director.

Failure to recognize potential problems could induce pneumothorax in a patient, depress a patient's respiratory drive, result in cardiac arrest, barotraumas (electrocution from poorly maintained equipment, or disease from improper infection control).

30. TO WHAT EXTENT DO PRACTITIONERS WORK INDEPENDENTLY (AS OPPOSED TO WORKING UNDER THE AUSPICES OF AN ORGANIZATION, AN EMPLOYER OR A SUPERVISOR)?

It is the intent of the medical and polysomnographic associations and organizations that polysomnography personnel work under the general supervision of a physician or medical director who is knowledgeable in sleep disorders. Polysomnography personnel who are not Registered Polysomnographic Technologists are suppose to work under the direct supervision of the physician, medical director or a Registered Polysomnographic Technologist. A responder to the RCB's survey indicated "the Association of Polysomnographic Technologists (APT) does not support the practice of Polysomnographic Technology by personnel who are inexperienced, untrained, or uneducated working in the profession of Polysomnographic Technology or any other health care profession. The training of a polysomnographic technician is of prime importance and under no circumstance should it be unsupervised. American Academy of Sleep Medicine accredited sleep disorders centers require a board-certified sleep specialist (or designee) to train polysomnographic technicians, with training periods lasting six months to one year."

Responders to the RCB's 2004 Survey indicated knowledge of individuals working independently in mobile units, in areas where there are no acute hospital based labs and or in areas where acute facilities have a back log of two months or more waiting time. Without the ability to regulate, the RCB can only guess at how many practitioners are working independently in hotel, office and mobile settings.

31. TO WHAT EXTENT DO DECISIONS MADE BY THE PRACTITIONER REQUIRE A HIGH DEGREE OF SKILL OR KNOWLEDGE TO AVOID HARM?

Again, it has been reported to the RCB in its survey that the APT believes personnel who are inexperience, untrained, or uneducated should not be working in the profession of Polysomnographic Technology.

One responder to the RCB's survey appropriately stated, "It is seriously dangerous when on-the-job trained sleep people do CPAP, BIPAP and O2 administration. They do not have a clue about work of breathing, flow, or any COPD complications, especially if they are working alone."

VI. FUNCTIONS AND TASKS OF THE OCCUPATION ARE CLEARLY DEFINED

32. DOES THE PROPOSED REGULATORY SCHEME DEFINE A SCOPE OF ACTIVITY WHICH REQUIRES LICENSURE, OR MERELY PREVENT THE USE OF A DESIGNATED JOB TITLE OR OCCUPATIONAL DESCRIPTION WITHOUT A LICENSE?

The proposed regulatory scheme clearly defines a scope of activity which requires licensure as a polysomnographic technologist or work permitted as a polysomnographic technologist applicant and exempts RCPs from polysomnography licensure.

33. DESCRIBE THE IMPORTANT FUNCTIONS, TASKS AND DUTIES PERFORMED BY PRACTITIONERS. IDENTIFY THE SERVICES AND/OR PRODUCTS PROVIDED.

Credentialed polysomnographic personnel, both the technologist, technician and the trainee, provide comprehensive evaluation and treatment of sleep disorders which involves polysomnography, diagnostic and therapeutic services or patient care and education. Each level performs the same functions but with varied levels of complexity and supervision.

However the RCB is proposing to regulate only one category, the "polysomnographic technologist." The RCB provides the following proposed definitions to identify the services to be provided and regulated:

"Polysomnography" means an order by a California physician or by written procedures and protocols approved by the medical director of a sleep disorder program and in accordance with federal and state laws and regulations, the process of analysis, attended monitoring and recording of physiologic data during sleep and wakefulness to assist in the assessment and diagnosis of sleep/wake disorders and other disorders, syndromes and dysfunctions that either are sleep related, manifest during sleep or disrupt normal sleep/wake cycles and activities.

"Polysomnography related respiratory care services" means the limited practice of respiratory care in the provision of polysomnography services which includes the diagnostic and therapeutic use of oxygen, noninvasive ventilatory assistance of spontaneously breathing patients and cardiopulmonary resuscitation, establishment of baseline oxyhemoglobin saturation, routine fitting of positive airway pressure mask or cannula, maintenance of nasal and oral airways that do not extend into the trachea, continuous observation, analysis and recording of carbon dioxide concentrations in respiratory gases, and other respiratory events, validation of respiratory-related data integrity, calibration of respiratory care devices, implementing appropriate interventions, including actions necessary for patient safety, and applying the knowledge and skills necessary to recognize and provide age specific respiratory care in the treatment, assessment, and education of neonatal, pediatric, adolescent, adult, and geriatric patients.

All of the following duties developed by a joint committee of the APT, BRPT, AASM and the ASET currently fall within the California Respiratory Care Practice Act:

- Calibrate (respiratory care) equipment;
- Perform physiologic calibrations (related to respiratory care procedures);
- Perform routine positive airway pressure (PAP) mask fitting;
- Maintain PAP and oxygen titration;
- Establish baseline oxyhemoglobin saturation;
- Document routine observations and clinical respiratory events;
- Implement appropriate interventions, including actions necessary for patient safety and therapeutic intervention, such as continuous and bi-level positive airway pressure and oxygen administration;
- Verify integrity of data (as it relates to respiratory care) (repeats the physiological and instrument calibrations); and
- Demonstrate the knowledge and skills necessary to recognize and provide age specific care in the treatment, assessment, and education of neonatal, pediatric, adolescent, adult, and geriatric patients (as it relates to respiratory care).

Trainees, technicians, other health care professionals and non-licensed persons who are working in sleep laboratories (and offices, mobiles, homes and hotels) may perform all or some of these tasks.

34. IS THERE A CONSENSUS ON WHAT ACTIVITIES CONSTITUTE COMPETENT PRACTICE OF THE OCCUPATION? IF SO, STATE AND DOCUMENT. IF NOT, WHAT IS THE BASIS FOR ASSESSING COMPETENCE?

Standards for polysomnography were first published by the American Thoracic Society **(ATS)** in 1988 specifically for cardiopulmonary sleep studies. Other organizations have since published guidelines that vary in scope and in the level of detail.

American Thoracic Society (ATS) Standards

Written in 1988, *Standards for Cardiopulmonary Sleep Studies* **(Appendix H)** provides, that since 1978, "respiratory physicians have become increasingly aware of the need to consider an evaluation of ventilation and gas exchange during sleep in patients with a variety of established or suspected cardiorespiratory disorders including the sleep apnea syndromes, chronic obstructive pulmonary disease, asthma, cystic fibrosis, interstitial lung disease, pulmonary hypertension, structural chest wall abnormalities, respiratory neuromuscular disorders and central hypoventilation syndromes." These standards provide indications for cardiopulmonary sleep studies, timing and number of sleep studies, measurement techniques, scoring and interpretation of data, and screening and ambulatory monitoring techniques.

In 1994, *Indications and Standards for Use of Nasal Continuous Positive Airway Pressure (CPAP) in Sleep Apnea Syndromes* **(Appendix I)** discuss the indications, complications and treatment criteria for adult and pediatric population. The consensus statement for adult treatment of obstructive sleep apnea with CPAP provides that is "should be based on the usual clinical evaluation and objective assessment of sleep and breathing" as described. These standards also note that the etiology (cause or origin of disease), clinical manifestations, and treatment of obstructive sleep apnea in the pediatric population are different from those in adults.

American Academy of Sleep Medicine (AASM)

The AASM began publishing "Clinical Practice Parameters" in 1992 and has compiled guidelines for 33 various practice parameters. The purpose of these practice parameters is to provide guidance and aid to physicians in the diagnosis and treatment of sleep disorders [http://www.aasmnet.org/practiceparameters.asp].

American Association for Respiratory Care (AARC) / Association of Polysomnographic Technologists (APT)

In 1995, the AARC-APT Clinical Practice Guideline **(Appendix J)** was developed jointly by the AARC Cardiopulmonary Diagnostics CPG Focus Group in conjunction with the APT. The guideline provides a description of polysomnography as well as indications, precautions, limitations/validation of results, resources, and infection control guidelines. Personnel qualifications are also provided with the understanding that all personnel should work under the direction of a physician specifically trained in the diagnosis and treatment of sleep disorders. Level II personnel should be credentialed or licensed as a Registered Polysomnographic Technician, a Registered Electroencephalographic Technologist, RCP or Registered Nurse.

California Thoracic Society (CTS)
In 2002, the CTS's position *paper "Pulmonary Physiology Laboratory Personnel Qualifications-Position Paper"* **(Appendix K)** categorizes pulmonary function personnel into three levels, with the top level being the "Senior/Supervising Pulmonary Function Technologist," to perform sleep studies.

APT/AASM/BRPT/ASET Joint Committee
In 2002, a joint committee of the APT**,** the AASM, the BRPT and the ASET addressed the minimum skills and competencies required for polysomnographic technologists and developed job descriptions identifying duties, qualifications and education for three levels of polysomnography personnel; trainee, technician and technologist. The skills, educational requirements, and duties have been accepted on a national basis and will be further addressed in Section VIII.

35. ARE INDICATORS OF COMPETENT PRACTICE LISTED IN RESPONSE TO QUESTION 34 MEASURABLE BY OBJECTIVE STANDARDS SUCH AS PEER REVIEW? GIVE EXAMPLES.

Yes, competent practice is measurable by peer review. For example, the Board of Registered Polysomnographic Technologists (BRPT) will investigate complaints and revoke a credential granted to an individual who successfully passed the examination if warranted. This, however, does not stop the individual from seeking employment in the field of polysomnography without the credential. The AASM began publishing practice parameters to provide guidance and aid to physicians in the diagnosis and treatment of sleep disorders. However, without regulation, the only recourse a physician or medical director has when dealing with incompetent practitioners is to fire them. This does not stop the incompetent practitioners from seeking employment in the polysomnography field elsewhere.

36. SPECIFY ACTIVITIES OR PRACTICES THAT WOULD SUGGEST THAT A PRACTITIONER IS INCOMPETENT. TO WHAT EXTENT IS PUBLIC HARM CAUSED BY PERSONAL FACTORS SUCH AS DISHONESTY? DOCUMENT.

Without regulation and the ability to track complaints, the Board can only suggest incidents that would imply a practitioner is incompetent or anticipate the public harm personal factors could cause. The following are some scenarios the Board anticipates may be happening in the polysomnography field based on real life error reports on equipment made to the FDA and in other regulated health care professions.

- The practitioner was conducting a sleep study on a patient and she failed to recognize the patient was experiencing symptoms of cardiac arrest. The practitioner did not call for the supervising physician in time and the patient died of heart failure.

- The practitioner did not choose the correct montage and channel parameters on the recording equipment while conducting a study on a patient. It was determined the patient did not have sleep apnea, however five months later the patient was driving at noon when she crossed over the white line killing herself and a young child in the other car.

- The practitioner failed to properly calibrate the recording equipment while performing a sleep study on a patient. It was later determined he did not suffer from narcolepsy. Two months later this individual was rushed to the emergency with severe head injuries he sustained after falling asleep at his drafting table at work.

- The practitioner failed to properly rinse and disinfect the equipment and this failure cased a patient to be sent to the emergency room with cracked and peeling skin on both sides of her nose which was later diagnosed as pressure necrosis (the localized death of living cells as from infection or the interruption of blood supply).

- The practitioner wondered if he was supposed to get the recordings correct this time. He wished his physician employer would tell him when to get the correct reading. This was the fourth time this patient had been referred for a sleep test at the physician's office.

- The practitioner worried that the patient was going to report him to his employer. He thought she was in a deep sleep and had inappropriately touched her. Now he wasn't so sure she was asleep. He was probably going to be fired again.

Seventy-three percent (73%) of responders to the RCB's 2004 Survey replied they believed it could result in serious patient harm or even patient death if inexperienced personnel performed polysomnography, citing the following:

- Immediate risk to patients of serious bodily harm during is limited to CPAP induced pneumothorax (a real but very rare complication);
- Depressing respiratory drive (with the possibility of consequences) when titrating supplemental 02 in patients with 02 retention;
- Failure to identify or recognize and take appropriate action in the event of a cardiac emergency;
- Subjecting patients to miserable initial experiences with CPAP as a result of incompetence on the part of technical personnel which may lead to patient refusal of further treatment and subsequent consequences of untreated sleep apnea;
- Risk of barotraumas (or electrocution from poorly maintained equipment), and
- Misdiagnoses utilizing insufficient CPAP can contribute to the patient's continued health deterioration.

Forty-six percent (46%) of survey responders answered in the affirmative when asked if they had heard of any cases where a patient had to be retested as a result of personnel failing to perform a test or treatment correctly or ensuring equipment was calibrated properly, citing the following reasons for retests:

- Poor skills;
- Poorly trained;
- Inadequate CPAP titration;
- Repeated CPAP titration;
- Untrained technician did not apply patient ground and brain waves and test could not be stage scored, and
- Instances where a patient won't retest and the interrupting physician is forced to formulate a plan of treatment when information from the test is incomplete or missing due to staff's lack of knowledge, skill or training.

Although most survey respondents did not actually know of cases where patients were victims of fraud, theft, battery, sexual misconduct, or harmed by practitioners under the influence of drugs or alcohol, the majority believed criminal background checks should be performed on all sleep study personnel and the possibility existed that patients could be harmed as outlined in the following table:

TABLE D. Patient Personal Rights Violations

Fraud/Theft	Alcohol Abuse	Drug Abuse	Battery	Sexual Misconduct
3.6	3.5	3.7	3.8	4.2

Rating on a scale of 1 to 5 with 5 being absolute possibility

VII. THE OCCUPATION IS CLEARLY DISTINGUISHABLE FROM OTHER OCCUPATIONS THAT ARE ALREADY REGULATED

37. WHAT SIMILAR OCCUPATIONS HAVE BEEN REGULATED IN CALIFORNIA?

Based on the "Salary, Demographic, and Educational Needs Survey Report" which was conducted for the Association of Polysomnographic Technologists (APT) the RCB's survey, and the number of estimated facilities in California, it is estimated that 30% of the current sleep technicians are licensed RCPs and 5% are licensed nurses.

38. DESCRIBE FUNCTIONS PERFORMED BY PRACTITIONERS THAT DIFFER FROM THOSE PERFORMED BY OCCUPATIONS LISTED IN QUESTION 37.

Polysomnography is the collective process of attended monitoring and recording physiologic data during sleep, including sleep-related respiratory disturbances, for the purposes of identifying and assisting in the treatment of sleep/wake disorders.

Pamela K. Minkley, CPFT, RRT, RPSGT, described the technology used in polysomnography in an article titled "Respiratory Care Practitioners and Sleep Medicine: Opportunities and Challenges," published in the May 1998 issue of *Respiratory Care*. She wrote:

> "Polysomnography borrows and adapts technology from electroneurodiagnostics, pulmonary diagnostics, respiratory care, biomedical science, and other fields. It requires adaptation of clinical aspects of neurology, pulmonary, and sleep medicine with aspects of gastrointestinal medicine, ear, nose, and throat medicine, urology, psychiatry, psychology, and social work. It is an amalgamation of skills that is a specialty unto itself - sleep medicine and technology.... **Respiratory care and electroneurodiagnostics contribute many of the educational competencies that provide a base upon which to build**."

It is estimated that consumers seeking sleep testing/treatment are in most cases (> 50%), diagnosed with or suspected of suffering from obstructive sleep apnea – to which the diagnostic and treatment services are within the practice of respiratory care. ***In addition, all of the respiratory-related***

monitoring involved in polysomnography and treatment of respiratory-related sleep disorders fall within the California Respiratory Practice Act.

39. INDICATE THE RELATIONSHIPS AMONG THE GROUPS LISTED IN RESPONSE TO QUESTION 37 AND PRACTITIONERS. CAN PRACTITIONERS BE CONSIDERED A BRANCH OF CURRENTLY REGULATED OCCUPATIONS?

Yes, they are a branch of respiratory care and a branch of electroneurodiagnostic, but electroneurodiagnostic technicians are not regulated.

40. WHAT IMPACT WILL THE REQUESTED REGULATION HAVE UPON THE AUTHORITY AND SCOPES OF PRACTICE OF CURRENTLY REGULATED GROUPS?

Licensed RCPs would have the option of adding the polysomnographic technologist (PSGT) designation to their current RCP license by obtaining credentialing from the Board of Registered Polysomnographic Technologists (BRPT) or the National Board for Respiratory Care. However, this designation would not be required for a RCP to perform polysomnography. The PSGT designation would entitle the RCP to also use the title and initials of the PGST.

The status of the PSGT designation would be solely dependant upon the status of the RCP license; cancelled, delinquent or current. All renewal and licensing requirements for a RCP are tied only to the RCP license – no new additional requirements would be imposed. If the RCP license cancels and the individual wanted to obtain an independent PSGT license, he or she would need to apply for licensure as a PSGT and meet those requirements.

Other licensed professionals (i.e. registered nurses) would continue to have the exemption that is provided in Business and Professions Code, section 3762 which provides: “Nothing in this chapter is intended to limit preclude, or otherwise interfere with the practices of other licensed personnel in carrying out authorized and customary duties and functions.”

41. ARE THERE UNREGULATED OCCUPATIONS PERFORMING SERVICES SIMILAR TO THOSE OF THE GROUP TO BE REGULATED? IF SO, IDENTIFY.

It is estimated that 65% of sleep technicians are unlicensed personnel. A number of providers contributing to the practice of polysomnography are ***unlicensed*** but educated electroneurodiagnostic technicians. However, there are also a significant, although unknown, number of other unlicensed individuals, including college students, who lack the education and training to competently perform polysomnography from all aspects. The RCB estimates there are 448 unlicensed personnel practicing at this time. There is currently one organization that offers a sleep technician credential that requires as little as 18 months of on-the-job training, under the supervision of **non-licensed** personnel, to qualify for the examination. However, this credential is not held by all nor required to be held by those practicing polysomnography.

42. DESCRIBE THE SIMILARITIES AND DIFFERENCES BETWEEN PRACTITIONERS AND THE GROUPS IDENTIFIED IN QUESTION 41.

All perform polysomnography. The differences are 1) competency, 2) licensure, 3) education, 4) training, and 5) supervision.

RCPs and registered nurses are licensed and regulated to ensure accountability, competency and enhance public safety protections. They are required to be knowledgeable of and follow consumer safety laws and regulations, such as infection control guidelines, and are subject to criminal background checks and discipline. Further, they must meet the education standards established for their professions and successfully pass licensure examinations to ensure they are competent. These individual may have also successfully completed the examination given by the Board of Registered Polysomnographic Technologists **(BRPT)** and obtained a credential in polysomnography.

The unlicensed practitioners, such as the electroneurodiagnostic technicians ***may*** be educated and trained, even credentialed by the BRPT, but they are not regulated. They are not held accountable for their actions nor are they required to be competent, knowledgeable of California law, and protect the public's safety. Failure to perform competently and protect the consumer holds little or no consequence for them.

The unlicensed, uneducated, and untrained individuals who are performing polysomnography are accountable only to their employer.

VIII. THE OCCUPATION REQUIRES POSSESSION OF KNOWLEDGE, SKILLS, AND ABILITIES THAT ARE BOTH TEACHABLE AND TESTABLE

43. IS THERE A GENERALLY ACCEPTED CORE SET OF KNOWLEDGE, SKILLS AND ABILITIES WITHOUT WHICH A PRACTITIONER MAY CAUSE PUBLIC HARM? DESCRIBE AND DOCUMENT.

In addition to the guidelines developed by many of the medical organizations and associations such as the American Association for Respiratory Care (AARC), the BRPT also includes the knowledge, skills and abilities that are fundamental to the performance of each task performed by, and tested, credentialed polysomnographic personnel in an examination candidate handbook which can be found in **Appendix L.** This examination is discussed in detail in Questions 49 and 50. The examination identifies a core set of knowledge, skills and abilities without which a practitioner may cause public harm.

Further, the Association of Polysomnographic Technologists (APT) has published core competencies to further identify the knowledge, skills, and outcome assessments necessary during polysomnography evaluations. The core competencies also identify the objectives, appropriate settings, indications and contraindications. Detailed information may be found in **Appendix M**. The core competencies are defined as follows:

- **Capnography** is the quantifiable method for measurement of carbon dioxide in the exhaled gas (End Tidal CO2 [EtCO2]) and skin (Transcutaneous CO2 [TcCO2]) during an overnight polysomnogram which **must** be performed in a facility-based sleep study laboratory, and not in the home or in a mobile facility. There is a potential for localized erythema or skin burns from electrodes a high heater temperatures.

- **Supplemental Low Flow Oxygen Titration in Polysomnographic Technology** is the administration of oxygen at concentrations greater than room air to reduce or eliminate hypoxemia that occurs during sleep. Supplemental low flow oxygen therapy can be delivered either with a nasal cannula or entrained in the circuit during titration of Nasal Continuous or Bi-Level Positive Airway Pressure (PAP) titration. The polysomnographic evaluation **must** be performed in a facility-based sleep disorders facility, and not in the home or in a mobile facility. Precautions must be taken for patients with chronic obstructive pulmonary disease because adding supplemental oxygen may lead to an increase in PaCO2 and a decrease in the drive to breath which impairs the hypoxic drive. Fire hazard is increased with the use of oxygen in the sleep disorders facility. Power outage can lead to inability to use the oxygen concentrator and adequate back up should be in place.

- **Positive Airway Pressure Titration in Polysomnographic Technology** is the delivery of positive air pressure through the nasal passage forming an air splint of the upper airway to provide continuous air exchange during sleep in patients with Obstructive Sleep Apnea/Hypopnoea Syndrome. The polysomnographic evaluation **must** be performed in a facility-based study laboratory, and not in the home or in a mobile facility.

- **Monitoring Pulse Oximetry in Polysomnographic Technology** is a well-establish non-invasive method of monitoring the percentage of hemoglobin (Hb) which is saturated with oxygen. This is done with a sensor usually attached to the patient's finger. This guideline is confined to the use of monitoring pulse oximetry in the sleep laboratory setting to identify those respiratory events that meet the sleep laboratory protocol and implement appropriate therapeutic intervention and **must** be performed in a facility-based sleep study laboratory, and not in the home or in a mobile facility.

- **Arrival Preparation and Electrode/Sensor Application in Polysomnographic Technology** provides that arrival preparations are those measures taken to set up the recording environment for a polysomnographic evaluation. Electrodes and sensor application is the process of attaching devices securely and comfortable to the patient for the measurement of multiple physiological parameters during the polysomnographic evaluation. Physiological calibrations is the process conducted pre and port testing where a series of instructions are given to the patient to elicit responses that are displayed on the polysomnogram and verify the signal integrity.

- **Polysomnographic Montages and Equipment Calibration and Function in Polysomnographic Technology** is the calibration process in which a known input standard is introduced into the acquisition system and the output to that standard is measured. The polysomnographic montage specifies the parameters recorded for data analysis and to assist in the identification of sleep/wake disorders.

- **Scoring Sleep States and Clinical Events in Polysomnographic Technology** defines scoring as the process of reviewing, analyzing, classifying and tabulating sleep staging and clinical events from the polysomnogram according to published professional standards and guidelines. Recordings are staged in 30 second epochs. Clinical events include, but not limited to, sleep related movements; arousals; cardiac arrhythmias; sleep disorder breathing; oxygen saturation level; esophageal pH; Carbon Dioxide (CO2) levels.

- **Maintenance, Cleaning, and Safety Precautions in Polysomnographic Technology** defines maintenance as tasks performed at manufacturer recommended intervals to assure the proper functioning of a device. Cleaning is the process of washing soiled items, and may include use of disinfecting or sterilization procedures. Safety precautions are those steps taken to minimize the risk of harm from potentially hazardous materials or situations.

44. WHAT METHODS ARE CURRENTLY USED TO DEFINE THE REQUISITE KNOWLEDGE, SKILLS AND ABILITIES? WHO IS RESPONSIBLE FOR DEFINING THESE KNOWLEDGE, SKILLS AND ABILITIES?

As previously stated, guidelines have been developed by the various medical associations and organizations establishing requisite knowledge, skills and abilities. In addition, many of these entities worked with the APT to define the core competencies as briefly outlined in Question 43 above and as defined in detail in **Appendix M.** The BRPT also includes the knowledge, skills and abilities in an examination candidate handbook which can be found in **Appendix L**.

The APT and the BRPT have assumed the responsibility for defining these knowledge, skills and abilities in an effort to promote continued competence of their profession, polysomnographic technology. More recently the National Board for Respiratory Care is taking an active role in this area as well in preparation to develop its own examination.

45. ARE THE KNOWLEDGE, SKILLS AND ABILITIES TESTABLE? IS THE WORK OF THE GROUP SUFFICIENTLY DEFINED THAT COMPETENCE COULD BE EVALUATED BY SOME STANDARD (SUCH AS RATINGS OF EDUCATION, EXPERIENCE OR EXAM PERFORMANCE)?

Yes, the knowledge, skills and abilities are testable and can be tested by exam performance. The Board of Registered Polysomnographic Technologists **(BRPT)** provides the "Registered Polysomnographic Technologist" examination and obtained accreditation by the National Organization for Competency Assurance (NOCA) in 2002 [NOCA was established in 1977 and is the leader in setting standards for credentialing organizations].

Currently the BRPT provides the only competency examination for sleep technologists. The National Board for Respiratory Care **(NBRC)** is in the process of developing its own competency examination for sleep technologists and anticipates its availability in 2009. The NBRC has long been accredited by the NOCA and is nationally-recognized for credentialing respiratory therapists and pulmonary function technologists since the 1960s.

46. LIST INSTITUTIONS AND PROGRAM TITLES OFFERING ACCREDITED AND NON-ACCREDITED PREPARATORY PROGRAMS IN CALIFORNIA. ESTIMATE THE ANNUAL NUMBER OF GRADUATES FROM EACH. IF NO SUCH PREPARATORY PROGRAMS EXIST WITHIN CALIFORNIA, LIST PROGRAMS FOUND ELSEWHERE.

In California there is one institution, Orange Coast College, which provides a formal education in polysomnography. Orange Coast College offers a 2-year polysomnography program as well as a 1-year add-on certificate to the respiratory care or Electroneurodiagnostic technology 2-year programs (refer to **Appendix N** for course requirement comparisons for each certificate/degree).

Orange Coast College reports 132 polysomnography graduates since its first graduation in May of 1993 as follows:

TABLE E. ORANGE COAST COLLEGE POLYSOMNOGRAPHY GRADUATES

Two Year Polysomnography Program	One Year Add-on Program for Respiratory Care	One Year Add-on for Electroneurodiagnostic Technology
112	12	8

There are approximately 15 polysomnography education programs in the United States, including those that are specifically designed as polysomnography programs and those respiratory care and electroneurodiagnostic programs with a polysomnography "endorsement" such as those available at Orange Coast College. There are also a handful of polysomnography training courses ranging in length from two days to two weeks.

Polysomnography educational programs are limited to a few recently accredited programs designed specifically to polysomnography and accredited respiratory care and electroneurodiagnostic programs with a "polysomnography endorsement." Graduates from all of these programs are considered viable candidates to fill sleep technician vacancies among those employers who value the knowledge and experience of educated employees. Polysomnography education as a whole, is in its infancy as demonstrated by the limited number of educational programs, the recent development of accreditation standards, and recent revisions to the entry requirements for the credentialing examination providing equity between electroneurodiagnostic and respiratory programs.

In April 2003, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) finalized accreditation standards for a one-year add-on polysomnography certificate complimenting existing respiratory care programs. Thereafter, also in 2003, the BRPT was accepted as a sponsoring member of the newly-formed Committee on Accreditation of Polysomnographic Technology within the CAAHEP to which they recently developed standards for stand-alone polysomnography programs.

47. APART FROM THE PROGRAMS LISTED IN QUESTION 46, INDICATE VARIOUS METHODS OF ACQUIRING REQUISITE KNOWLEDGE, SKILL AND ABILITY. EXAMPLES MAY INCLUDE APPRENTICESHIPS, INTERNSHIPS, ON-THE-JOB TRAINING, INDIVIDUAL STUDY, ETC.

Many individuals who are performing polysomnography receive on-the-job training. The credentialing examination accepts as one pathway, 18 months of paid work experience to qualify to sit for the examination. Unfortunately the extent of training depends largely on the hiring facility and its training protocols. While standards are in place, those standards also allow unlicensed personnel to provide oversight of this on-the-job training.

48. ESTIMATE THE PERCENTAGE OF CURRENT PRACTITIONERS TRAINED BY EACH OF THE ROUTES DESCRIBED IN QUESTIONS 46 AND 47.

Based on the very limited number of education programs and data in Table A (on page 2), the Board believes that 35% of practitioners have a respiratory care or nursing education, 15% have an electroneurodiagnostic education and 50% have no classroom education. All candidates have on-the-job training. Those with no formal education have more on-the-job training than those with a formal education.

49. DOES ANY EXAMINATION OR OTHER MEASURE CURRENTLY EXIST TO TEST FOR FUNCTIONAL COMPETENCE? IF SO, INDICATE HOW AND BY WHOM EACH WAS CONSTRUCTED AND BY WHOM IT IS CURRENTLY ADMINISTERED. IF NOT, INDICATE SEARCH EFFORTS TO LOCATE SUCH MEASURES.

While the National Board for Respiratory Care is in the process of developing its own competency examination (anticipated to be available by 2009), the BRPT is currently the only examiner of functional competence.

The Registered Polysomnographic Technologist Examination assesses the professional competence of practitioners performing polysomnography and associated therapeutic interventions. The BRPT credentialing program is accredited by the National Commission of Certifying Agencies. Successful completion of the examination is required for an individual to earn the Registered Polysomnographic Technologist credential.

The BRPT performs an international role delineation survey, or “job analysis” of the profession, on a 5-year cycle to ensure that examination development reflects current practices in the field. Current exam content is based on a role delineation survey completed in 2004.

The 2004 role delineation survey was conducted to determine appropriate content for the Registered Polysomnographic Technologist examination, in accordance with the 1999 “Standards for Educational and Psychological Testing” (American Education Research Association, American Psychological Association, and National Council on Measurement in Education) as well as the 1978 “Uniform Guidelines on Employee Selection Procedures” (Equal Employment Opportunity Commission et al.).

The participants in the job analysis study constituted an internationally representative group of practitioners involved in polysomnographic technology. Survey participants using scales of task criticality and frequency, as defined in the role delineation survey, rated the job responsibility domains

and task descriptions. Knowledge, skill and abilities that are fundamental of the performance of each task are represented by the knowledge/skills/abilities (KSA) statements listed in the content outline. The results of the role delineation survey were used to construct the Content Outline of the BRPT examination which can be found in Question 50.

50. DESCRIBE THE FORMAT AND CONTENT OF EACH EXAMINATION LISTED IN QUESTION 49. DESCRIBE THE SECTIONS OF EACH EXAMINATION. WHAT COMPETENCIES ARE EACH DESIGNED TO MEASURE? HOW DO THESE RELATED TO THE KNOWLEDGE, SKILLS AND ABILITIES LISTED IN QUESTION 43?

The examination consists of five domains that identify the principal areas of responsibility or activity comprising polysomnography. Each domain includes a brief behavioral description and has one or more task statements associated with it. The task statements define a specific, goal-directed set of activities having a common objective. Each task statement has associated with it several knowledge/skills/abilities (KSA) statements that define the basic knowledge and skill base required to perform the task. Knowledge statements define organized bodies of information, usually of a factual or procedural nature, which if applied, make performance of the task possible. Skill statements define proficient manual, verbal, or mental manipulation of data, people or things. Skills embody observable, quantifiable, and measurable performance parameters.

The examination covers the following domains and tasks:

- **Domain I: Analysis of Pre-Testing Information**

  Task 1. Assess the physician's polysomnography request in order to determine its completeness and appropriateness to ensure valid data collection.

  Task 2. Assess the patient's history to determine if special testing requirements are necessary (e.g. special bed, ancillary equipment).

  Task 3. Review the patient's medical history and interview the patient to anticipate the nature and likelihood for medical intervention.

  Task 4. Inventory the supplies provided to ensure the requirements of the study are met.

  Task 5. Select indicated ancillary equipment in order to optimize data collection.

- **Domain II: Study Performance**

  Task 1: Choose the montage and channel parameters on the recording equipment in order to collect data properly.

  Task 2. Calibrate the recording equipment to assure proper functioning (e.g., polysomnograph, ancillary devices) before, during, and after testing.

  Task 3. Explain to the patient the testing procedures and possible interventions that might occur in order to prepare him or her for testing.

  Task 4. Determine the placement site and properly apply the sensors according to established guidelines in order to consistently record quality data.

Task 5. Acquire, verify, and document physiological calibrations in order to demonstrate accurate patient data collection.

Task 6. Recognize and document relevant data (e.g., lights off and lights on, body position, artifacts, life-threatening events, cardiac/EEG abnormalities, respiratory disturbances) throughout the recording process in order to assist in data analysis.

Task 7. Differentiate true physiologic data from recording artifacts and correct artifacts when appropriate, in order to optimize data collection.

Task 8. Recognize the need for interventions (e.g. PAP, O2 titration, CPR) and perform them according to established guidelines in order to provide appropriate patient care.

Task 9. Summarize Polysomnography and clinical observations in order to assist data interpretation.

Task 10. Apply standard precautions throughout the patient's evaluation in order to prevent the spread of infection to patients and staff.

- **Domain III: Scoring**

Task 1. Identify appropriate documents and data for use in analysis.

Task 2. Score sleep stages and arousals in order to facilitate interpretation.

Task 3. Score respiratory events in order to facilitate interpretation.

Task 4. Score movement events in order to facilitation interpretation.

Task 5. Score miscellaneous events in order to facilitation interpretation.

Task 6. Generate and validate a report of the scoring of objective and subjective data in order to summarize the polysomnographic procedure.

Task 7. Use of acceptable methods to archive data in order to ensure long-term storage and accessibility.

- **Domain IV: Patient Support and Education Activities**

Task 1. Coordinate PAP orders with home healthcare provider to facilitate appropriate treatment.

Task 2. Suggest solutions to patients who have problems with PAP equipment to maximize PAP benefits.

Task 3. Work under the direction of a physician to provide information to the patient regarding his or her treatment.

Task 4. Provide information to the public regarding sleep disorders medicine in order to facilitate awareness.

- **Domain V: Site Management**

  Task 1. Inspect Polysomnography and ancillary equipment based on accepted standards in order to assure proper operation and safety.

  Task 2. Apply cleaning and sterilization procedures on reusable laboratory equipment based on established precautions in order to assure patient safety and infection control.

  Task 3. Follow policies in order to respond appropriately to hazardous situations (e.g., fire, spills, weather, earthquake).

  Task 4. Follow standards in order to assess quality assurance (e.g., inter-scorer reliability. Multidisciplinary patient case review).

  Task 5. Maintain patient records using government and industry regulations in order to allow appropriate access and protect confidentiality.

The Board of Registered Polysomnographic Technologists **(BRPT)** 2006 Candidate Handbook can be found in **Appendix L.** The guide contains the required knowledge and skills which are listed after each task. The study guide also contains the weight of the exam by domain for scoring purposes.

The BRPT examination tests all the knowledge, skills and abilities listed in the Association of Polysomnographic Technologists (APT)'s core competencies found in Question 43.

51. IF MORE THAN ONE EXAMINATION IS LISTED ABOVE, WHICH STANDARD DO YOU INTEND TO SUPPORT? WHY? IF NONE OF THE ABOVE, WHY NOT, AND WHAT DO YOU PROPOSE AS AN ALTERNATIVE?

Currently the only existing examination is the Registered Polysomnographic Technologist credentialing examination established by the BRPT. Until future examinations are developed and approved, the RCB believes this examination is valid and reliable and intends to support the use of it.

IX. ECONOMIC IMPACT OF REGULATION IS JUSTIFIED

52. HOW MANY PEOPLE ARE EXPOSED ANNUALLY TO THIS OCCUPATION? WILL REGULATION OF THE OCCUPATION AFFECT THIS FIGURE?

According to the National Sleep Foundation two-thirds of the nation's adult population and two thirds of the nation's children suffer from some form of sleep deprivation. The American Sleep Apnea Association estimates 18 million adults and children suffer from some form of sleep apnea. However, both organizations indicate many individuals are not aware they suffer from a sleep disorder.

TABLE F. CALIFORNIA POTENTIAL EXPOSURE TO POLYSOMNOGRAPHY

Age Level	Californians		Number of Californians With Potential Sleep Problems
	% Based on 2004 Census	Population 36,132,147 Based on 2005 Census	Based on Sleep Associations 2/3 children & 2/3 Adults
Under 5 years	7.3	2,637,647	1,756,673
Under 18 years	26.7	9,647,283	6,425,090
18 to 64 years	55.3	19,981,077	13,307,397
65 and older	10.7	3,866,140	2,574,849
TOTAL	*100.0*	*36,132,147*	*24,064,009*

As indicated in the last column of the above table, there is a distinct possibility that over 24 million Californians should be receiving some sort of treatment for sleep disorders.

Regulation of the profession will increase its awareness and bring about greater confidence in the competency of polysomnography service providers, thereby increasing the number of individuals utilizing the service.

53. WHAT IS THE CURRENT COST OF THE SERVICE PROVIDED? ESTIMATE THE AMOUNT OF MONEY SPENT ANNUALLY IN CALIFORNIA FOR THE SERVICES OF THIS GROUP. HOW WILL REGULATION AFFECT THESE COSTS? PROVIDE DOCUMENTATION FOR YOUR ANSWERS.

Respondents to the RCB's 2004 Survey provided billing information of which 14 responded there figures were "accurate." They were asked to provide a range of services from those with the lowest, medium, to highest costs and indicate whether this is an amount that is expected to be paid primarily by health insurance or by a patient; if billed to Medicare and/or MediCal, and the amount reimbursed.

Based on these 14 responses, most polysomnography services are paid by insurance companies as follows:

TABLE G. CURRENT COSTS OF SERVICE PROVIDED AND MEDICARE/MEDICAL REIMBURSEMENT

Service	Amount Billed	Medicare Reimbursement Amount	MediCal Reimbursement Amount
95810 Diagnostic Polysomnography	$2,194	$542	$250
95811 Polysom w/ CPAP	$2,118	$560	$350

The field of polysomnography is in its infancy when compared to other healthcare fields and financial data is not readily available. The RCB is unable to accurately determine the amount of money spent annually in California on sleep studies. CBS reported in April of this year in an article entitled *Chronic Sleep Problems Affect Millions* that "studies in the 1990s estimated the cost of medical care for sleep disorders at $15.9 billion…." In addition, it said, "...fatigue is estimated to cost businesses roughly $150 billion a year in lost productivity and mishaps, and damage from motor vehicle accidents involving tired drivers amounts to at least $48 billion a year." The Sleep Disorder Center of Virginia reports sleep-related accidents cost as much as $46 billion annually.

The RCB anticipates regulation will increase costs only because awareness will increase the number of consumers having sleep studies. The RCB does not anticipate that requiring unlicensed practitioners to become licensed will cause a significant increase in the cost of the studies. Further, the RCB believes the more consumers are aware of and seek treatment of sleep disorders, the greater the reduction in the reported billions now costing the consumers, their employers, and their insurance companies for sleep related accidents and injuries and lost of productivity. The better consumers sleep throughout the night, the less likely they are to be unproductive, injured on the job or in car accidents.

Respondents to the RCB's 2004 survey were divided when asked if they anticipated regulation of polysomnographic technicians would increase the cost of services. Thirty-eight percent (38%) responded yes cost would increase, 28% said they would not increase and the remaining 34% were not sure.

54. OUTLINE THE MAJOR GOVERNMENTAL ACTIVITIES YOU BELIEVE WILL BE NECESSARY TO APPROPRIATELY REGULATE PRACTITIONERS. EXAMPLES MAY INCLUDE SUCH PROGRAM ELEMENTS AS: QUALIFICATIONS EVALUATION, EXAMINATION DEVELOPMENT OR ADMINISTRATION, ENFORCEMENT, SCHOOL ACCREDITATION, ETC.

The RCB needs the legal authority to regulate this practice to offer some assurance to the public that the regulated individual is competent to provide certain services in a safe and effective manner through the examination process, ensures the public is protected from unscrupulous, incompetent and unethical practitioners by conducting criminal back ground checks, and provides a means by which individuals who fail to comply with the profession's standards can be disciplined, including the revocation of their licenses.

55. PROVIDE A COST ANALYSIS SUPPORTING REGULATORY SERVICES TO THIS OCCUPATION. INCLUDE COSTS TO PROVIDE ADEQUATE REGULATORY FUNCTIONS DURING THE FIRST THREE YEARS FOLLOWING IMPLEMENTATION OF THIS REGULATION. ASSURE THAT AT LEAST THE FOLLOWING HAVE BEEN INCLUDED:

A. COSTS OF PROGRAM ADMINISTRATION, INCLUDING STAFFING
B. COSTS OF DEVELOPING AND/OR ADMINISTERING EXAMINATIONS
C. COSTS OF EFFECTIVE ENFORCEMENT PROGRAMS.

Table H. Proposed Expenditures

Expenditure	Start Up Year 1	Year 2	Year 3	Year 4
Personnel (Salary & Benefits) 2.25 PYs	**$130,000**	**$160,000**	**$170,000**	**$175,000**
Administration	**$50,000**	**$65,000**	**$65,000**	**$75,000**
Enforcement	**$0**	**$25,000**	**$50,000**	**$75,000**
Total Proposed Costs	***$180,000***	***$250,000***	***$285,000***	***$325,000***

56. HOW MANY PRACTITIONERS ARE LIKELY TO APPLY EACH YEAR FOR CERTIFICATION IF THIS REGULATION IS ADOPTED? IF SMALL NUMBER WILL APPLY, HOW ARE COSTS JUSTIFIED?

Based on the figures shown in Table A (page 2) the RCB anticipates there will be at least 448 unlicensed personnel applying for licensure if legislation is enacted. Further, at least 44 RCPs may choose to add the PSGT designation to their existing RCP license. As awareness of polysomnography grows, education programs are expected to flourish and it is estimated the RCB would have a minimum of 250 new applicants each year. Following are estimated fee amounts and their revenue based on these assumptions taking into considerations the expenditures shown above.

Table I. Estimated Revenue

Revenue	Fee	Start Up Year 1		Year 2		Year 3		Year 4	
		Work load	Revenue	Work load	Revenue	Work load	Revenue	Work load	Revenue
Application Fee	$250	0	$0	448	$112,000	250	$62,500	250	$62,500
Extended Work Permit Fee	$200	0	$0	250	$50,000	250	$50,000	250	$50,000
Initial License Fee	$200	0	$0	250	$50,000	250	$50,000	250	$50,000
License Renewal	$400	0	$0	100	$40,000	350	$140,000	500	$200,000
Add RPSGT Title Only	$100	0	$0	44	$4,400	10	$1,000	10	$1,000
Totals			***$0***		***$256,400***		***$303,500***		***$363,500***

57. DOES ADOPTION OF THE REQUESTED REGULATION REPRESENT THE MOST COST-EFFECTIVE FORM OF REGULATION? INDICATE ALTERNATIVES CONSIDERED AND COSTS ASSOCIATED WITH EACH.

The RCB believes adoption of the proposed regulation would be the most cost-effective form of providing the greatest protection to consumers. It will ensure competent practitioners, document direct oversight, allow for criminal background checks, and provide a mechanism in which to discipline or "revoke" privileges to practice polysomnography for those individuals who harm California consumers.

Alternative 1: Enforce existing law. **Estimated Cost (less any revenue/reimbursement): $0**

This alternative would require all personnel performing any "polysomnography related respiratory care services" to be licensed as a RCP. This alternative would, because respiratory care is so intertwined in polysomnography, virtually require a RCP license to practice polysomnography.

Costs would be associated with the RCB needing to enforce existing law. The RCB would need to issue cease and desist letters and/or issue citations with abatement and fine for the unlicensed practice of respiratory care. The RCB may have expenditures to defend those citations and fines appealed. However, fine amounts would be expected to cover associated expenses.

Alternative 2: Provide exemption from the Respiratory Care Practice Act to allow sleep credentialed personnel to perform polysomnography, including "polysomnography related respiratory care services."

Estimated Cost (less any revenue/reimbursement): $0

This alternative would allow approximately two-thirds of the current estimated workforce to continue performing polysomnography without licensure. However, this alternative would eliminate any new personnel from being allowed to gain work experience needed to qualify for the credentialing examination. Additionally, this alternative does not provide for criminal background checks and a central organization to track practitioner competence/performance and a means to adjudicate consumer complaints. The RCB would still need to issue cease and desist letters and/or issue citations with abatement and fine for the unlicensed practice of respiratory care for those individuals not credentialed and not licensed. However, fine amounts would be expected to cover associated expenses.

Alternative 3: Provide exemption from the Respiratory Care Practice Act to allow the performance of polysomnography by any person under the direct supervision of a licensed physician.

Estimated Cost (less any revenue/reimbursement): $0

This alternative would provide that the licensed physician providing oversight would be held responsible for unlicensed personnel performing polysomnography. It would result in different standards for competency and cannot ensure direct supervision is actually provided. This alternative would for the most part, not change any existing practices including lack of criminal background checks of unlicensed personnel as well as the inability to discipline or "revoke" privileges to practice

polysomnography when incompetence or criminal behavior is found. The RCB would not incur any costs associated with this alternative.

Alternative 4: Establish a New Licensure Category for Polysomnographic Technologist.

Estimated Cost (less any revenue/reimbursement): see Questions 55 and 56

This alternative would create one new licensure category within the following framework:

I. DEFINITIONS

A. "Polysomnography" means an order by a California physician or by written procedures and protocols approved by the medical director of a sleep disorder program and in accordance with federal and state laws and regulations, the process of analysis, attended monitoring and recording of physiologic data during sleep and wakefulness to assist in the assessment and diagnosis of sleep/wake disorders and other disorders, syndromes and dysfunctions that either are sleep related, manifest during sleep or disrupt normal sleep/wake cycles and activities.

B. "Polysomnography related respiratory care services" means the limited practice of respiratory care in the provision of polysomnography services which includes the diagnostic and therapeutic use of oxygen, noninvasive ventilatory assistance of spontaneously breathing patients and cardiopulmonary resuscitation, establishment of baseline oxyhemoglobin saturation, routine fitting of positive airway pressure mask or cannula, maintenance of nasal and oral airways that do not extend into the trachea, continuous observation, analysis and recording of carbon dioxide concentrations in respiratory gases, and other respiratory events, validation of respiratory-related data integrity, calibration of respiratory care devices, implementing appropriate interventions, including actions necessary for patient safety, and applying the knowledge and skills necessary to recognize and provide age specific respiratory care in the treatment, assessment, and education of neonatal, pediatric, adolescent, adult, and geriatric patients.

C. "**Sleep disorder program**" means any sleep disorder center, laboratory, facility, home or any other area where polysomnography is conducted and such program is under the supervision of a California licensed physician or medical director who is responsible for patient care provided in such center or laboratory.

D. Define "Medical Director" *as it relates to polysomnography services* as follows:

"**Medical director"** means a physician and surgeon who is a member of a health care facility's active medical staff, who specializes in sleep medicine, is knowledgeable in respiratory care, and is licensed to practice medicine pursuant to California Business and Professions Code Chapter 5.

II. PSGT TITLE DESIGNATION FOR RESPIRATORY CARE PRACTITIONERS (RCP) - OPTIONAL

RCPs would have the option of adding the PSGT designation to their current RCP license. However, this designation would not be required to perform polysomnography. The PSGT designation would entitle the RCP to also use the title and initials of the PSGT.

The status of the PSGT designation would be solely dependant upon the status of the RCP license; cancelled, delinquent or current. All renewal and licensing requirements for a RCP are tied only to the RCP license – no new additional requirements would be imposed. If the RCP license cancels and the individual wanted to obtain an independent PSGT license, he or she would need to apply for licensure as a PSGT and meet those requirements.

A. Requirements for Initial Designation

1. Current Licensure as a RCP **AND** successful completion of the National Board for Respiratory Care (NBRC) or the Board of Registered Polysomnographic Technologists (BRPT) polysomnography competency examination.

III. CREATE NEW LICENSE CATEGORY – POLYSOMNOGRAPHIC TECHNOLOGIST (PSGT)

A. Supervision

1. The PSGT works under the (general) supervision of a medical director.

B. Scope of Practice

Those services defined as “polysomnography” and “polysomnography related respiratory care services.”

C. Requirements

1. Current licensure as a California RCP **OR**
2. Graduation from an accredited respiratory care program **OR**
3. Graduation from an accredited electroneurodiagnostics program **OR**
4. Graduation from a polysomnography educational program approved by the board **OR**
5. 18 months (3000 hours) of full-time paid work experience as a “polysomnographic technologist applicant” including 1000 hours in “polysomnography related respiratory care services”

   AND

6. Successful completion of the BRPT or NBRC polysomnography examinations **AND**
7. High School Graduate or its equivalent **AND**
8. 18 years or older **AND**
9. Current CPR certificate **AND**
10. Criminal Background Clearance **AND**
11. Any other educational courses, clinical practice or work experience identified by the RCB through regulation.

D. License Renewal

1. Every two years
2. Require 15 hours of CE
3. Include conviction statement
4. Include statement to verify CPR current

IV. WORK PERMIT AS A POLYSOMNOGRAPHIC TECHNOLOGIST APPLICANT (PSGA)

Individuals who apply for the PSGT license who meet all the requirements with the exception of the education and successful completion of the exam, may request a work permit to gain paid work experience necessary for licensure. Experience earned toward qualifying for the PSGT license must be paid and must be while the applicant maintains a current work permit (the RCB will grandfather in any past paid experience up to 24 months prior to enactment of proposed licensure legislation).

A. Supervision

1. The PSGA works under the direct supervision of a California licensed physician, a California licensed respiratory care practitioner, or a licensed California Respiratory Polysomnographic Technologist.

2. Direct supervision as used in this section means the supervising person shall be assigned to the PSGA, shall be on the premises where such polysomnographic services are provided and shall be immediately available in the patient area.

B. Scope

The PSGA may perform those diagnostic and therapeutic procedures defined as "polysomnography" and "polysomnography respiratory care related services," with the exception that the PSGA is not authorized to make assessments.

C. Requirements

Staff must verify that the following requirements have been met satisfactorily:

1. Meet all requirements for the PSGT license listed between nos. 7 and 11
2. Provide employer information
3. Provide names/credentials for "direct supervision"
4. Employer and "direct supervision" acknowledgment

D. Work Permits

1. Initial work permit issued for a period of six months
2. Extended work permit
    a. Issued in one-year increments not to exceed 2 ½ years from the start date of the initial work permit
    b. Extended work permits require a written request which includes:
        i. Conviction statement
        ii. Verification of current CPR
        iii. Employer information
        iv. Names/credentials for "direct supervision"
        v. Employer and "direct supervision" acknowledgment

V. CONTINUE EXISTING EXEMPTIONS

The existing exemptions in the Respiratory Care Practice Act would remain as currently written. These include other licensed professions practicing within their scope, self practice, students, etc.

VI. MISCELLANEOUS PROVISIONS

1. Must maintain current certification in CPR.
2. Clarify that a PSGT or PSGA applicant may not provide respiratory care beyond "polysomnography related respiratory care services" as defined above.
3. Clarify that a PSGT or PSGA applicant may only provide services within his/her scope of practice in conjunction with a "sleep disorders program" as defined above.
4. All provisions of the RCPA would apply equally to PSGTs and PSGAs.
5. Replace RCP appointed by the Senate Rules Committee with a PSGT or RCP with a PSGT designation (either while vacant or upon the appointment expiration date of a filled position).